

US3232157 (Prod: MediSync Clinical Research Hattiesburg Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:11:01

All time stamps listed in this document are displayed in GMT

US3232157

**Form: Participant Creation**

**Data signed: (b) (4) 02 Apr 2021 14:15:53**

**Generated On: 09 Jun 2021 16:11:01**

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[Participant ID](#)

US3232157

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

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US3232157

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	SCRN

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US3232157

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
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

US3232157

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Date of Informed Consent (*dd MMM yyyy*) 9 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3232157

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Did the participant meet all eligibility criteria?

Yes

No

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US3232157

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Were any significant conditions reported?

Yes

No

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US3232157

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Condition	LASER VISION CORRECTION
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 (2)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Condition	SLEEP APNEA
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 (4)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Condition	FREQUENT BLOOD DONOR
Start date (dd MMM yyyy)	15 MAR 2020
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)	15 MAR 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Condition	OSTEOARTHRITIS
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 (9)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Condition	RECURRENT BACK PAIN
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 (10)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Condition	CERVICAL SURGERY
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Condition	HERPES SIMPLEX VIRUS 2 (FACE)
Start date (dd MMM yyyy)	29 AUG 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3232157

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:35 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 13:35
Height ( <i>xxx.x</i> )	179 cm
Weight ( <i>xxx.x</i> )	80.7 kg
BMI ( <i>xxx.x</i> )	25.18648 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

9 SEP 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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US3232157

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

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**Specify** \_\_\_\_\_

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

<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>	True
<b>Specify</b>	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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	VISIT1

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US3232157

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 111003

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) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Height	ND - Not Done
Weight	ND - Not Done

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US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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 ( <i>dd MMM yyyy</i> )	9 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:35 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 13:35
Temperature ( <i>xxx.x</i> )	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	46 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:40 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 14:40
Temperature ( <i>xxx.x</i> )	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG

US3232157

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

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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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US3232157

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 14:20 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 14:20

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) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Was the sample collected? Yes   
No

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Collection date (*dd MMM yyyy*) 9 SEP 2020

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Collection time (*00:00-23:59*) 14:10 (24 HR)

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Collection date and time (derived) 9 SEP 2020 14:10

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US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Collection date ( <i>dd MMM yyyy</i> )			9 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:45	9 SEP 2020 13:45
Nasopharyngeal Swab 2	No		

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US3232157

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 SEP 2020 14:40

PC Close Date & Time

09 SEP 2020 17:10

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**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 97.9 °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 09 SEP 2020 18:58  
PC Open Date & Time 09 SEP 2020 18:05  
PC Close Date & Time 10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 SEP 2020 19:54
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 SEP 2020 17:16
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp 13 SEP 2020 10:02

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.5 °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 13 SEP 2020 21:58

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 SEP 2020 01:14
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 SEP 2020 01:34
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59



US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**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

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

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

- Yes
- No

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

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

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

PC Open Date & Time

09 SEP 2020 14:40

PC Close Date & Time

09 SEP 2020 17:10

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**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

09 SEP 2020 19:01

PC Open Date & Time

09 SEP 2020 18:05

PC Close Date & Time

10 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 2

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	10 SEP 2020 19:55
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 3

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

11 SEP 2020 17:17

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

13 SEP 2020 10:05

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 5

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

13 SEP 2020 21:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 6

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

15 SEP 2020 01:14

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 7

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

16 SEP 2020 01:35

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

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

No

Yes

PC Time stamp

PC Open Date & Time

09 SEP 2020 14:40

PC Close Date & Time

09 SEP 2020 17:10

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

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

No   
Yes

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PC Time stamp	09 SEP 2020 19:01
PC Open Date & Time	09 SEP 2020 18:05
PC Close Date & Time	10 SEP 2020 11:59

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US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

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	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 19:55
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

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US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

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

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US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

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	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 10:05
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

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US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

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	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 21:59
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

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US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

---

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 01:14
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

---

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

---

	Yes <input type="checkbox"/>
PC Time stamp	16 SEP 2020 01:35
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

---



US3232157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3232157

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3232157

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3232157

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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	VISIT2

---

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

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 ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	12:19 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:19
Temperature ( <i>xxx.x</i> )	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	64 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Diastolic Blood Pressure units	MMHG



US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:20 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 13:20
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	53 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG

US3232157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

7 OCT 2020

---

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

---

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

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) 7 OCT 2020

What was the treatment time? (00:00-23:59) 13:03 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 13:03

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

US3232157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 7 OCT 2020

---

Collection time (*00:00-23:59*) 12:30 (24 HR)

---

Collection date and time (derived) 7 OCT 2020 12:30

---

US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

---

Collection date ( <i>dd MMM yyyy</i> )			7 OCT 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:23	7 OCT 2020 12:23
Nasopharyngeal Swab 2	No		

---

US3232157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**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 97.5 °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 07 OCT 2020 13:23

PC Open Date & Time 07 OCT 2020 13:23

PC Close Date & Time 07 OCT 2020 15:53

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**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 98.5 °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 07 OCT 2020 19:22  
PC Open Date & Time 07 OCT 2020 16:48  
PC Close Date & Time 08 OCT 2020 11:59



US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 OCT 2020 17:44
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 OCT 2020 17:25
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	10 OCT 2020 21:10
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 OCT 2020 17:52
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 OCT 2020 18:32
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**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 14 OCT 2020 07:09

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**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

07 OCT 2020 13:25

PC Open Date & Time

07 OCT 2020 13:23

PC Close Date & Time

07 OCT 2020 15:53

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**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

07 OCT 2020 19:25

PC Open Date & Time

07 OCT 2020 16:48

PC Close Date & Time

08 OCT 2020 11:59



US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 2

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	08 OCT 2020 17:45
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 3

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

09 OCT 2020 17:26

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 4

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	10 OCT 2020 21:10
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 5

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	11 OCT 2020 17:52
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 6

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

12 OCT 2020 18:32

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	14 OCT 2020 07:10
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

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

No   
Yes

---

PC Time stamp	07 OCT 2020 13:26
PC Open Date & Time	07 OCT 2020 13:23
PC Close Date & Time	07 OCT 2020 15:53

---



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

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

No

Yes

---

PC Time stamp	07 OCT 2020 19:25
PC Open Date & Time	07 OCT 2020 16:48
PC Close Date & Time	08 OCT 2020 11:59

---

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

---

	Yes <input type="checkbox"/>
PC Time stamp	08 OCT 2020 17:45
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

---

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

---

	Yes <input type="checkbox"/>
PC Time stamp	09 OCT 2020 17:26
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

---

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

---

	Yes <input type="checkbox"/>
PC Time stamp	10 OCT 2020 21:11
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

---



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

---

	Yes <input type="checkbox"/>
PC Time stamp	11 OCT 2020 17:52
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

---

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

---

	Yes <input type="checkbox"/>
PC Time stamp	12 OCT 2020 18:33
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

---

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

---

	Yes <input type="checkbox"/>
PC Time stamp	14 OCT 2020 07:10
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

---

US3232157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

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*

---

---

US3232157

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3232157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3232157

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 OCT 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3232157

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:23

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 NOV 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

---

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	04 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	12:35 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 12:35
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	54 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3232157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

4 NOV 2020

---

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

---

US3232157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 4 NOV 2020

---

Collection time (*00:00-23:59*) 12:34 (24 HR)

---

Collection date and time (derived) 4 NOV 2020 12:34

---



US3232157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Feb 2021 16:11:24

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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 16 NOV 2020 06:36:46

Patient Cloud Open Date & Time 16 NOV 2020 00:01

Patient Cloud Close Date & Time 20 NOV 2020 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 75

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	01 DEC 2020 10:27:52
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	04 DEC 2020 07:38:11
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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	13 DEC 2020 12:16:08
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 DEC 2020 06:16:48
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 110

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3232157**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2020 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 117

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 01 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#) 05 JAN 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
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	08 JAN 2021 09:36:43
Patient Cloud Open Date & Time	08 JAN 2021 00:01

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 <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	15 JAN 2021 07:59:36
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 08:04:34
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 145

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

No

Yes

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

No

Yes

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

Date and time of submission 01 FEB 2021 09:03:29

Patient Cloud Open Date & Time 29 JAN 2021 00:01

Patient Cloud Close Date & Time 02 FEB 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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 05 FEB 2021 06:29:12

Patient Cloud Open Date & Time 05 FEB 2021 00:01

Patient Cloud Close Date & Time 09 FEB 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 <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	12 FEB 2021 07:57:53
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

<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	19 FEB 2021 06:42:11
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 <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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 FEB 2021 18:01:13
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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	07 MAR 2021 13:54:23
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 187

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

Date and time of submission

<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAR 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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	19 MAR 2021 08:06:26
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 <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	29 MAR 2021 08:25:44
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 208

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 <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	12 APR 2021 19:51:23
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 07:30:54
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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 23 APR 2021 07:48:03

Patient Cloud Open Date & Time 23 APR 2021 00:01

Patient Cloud Close Date & Time 27 APR 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 <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	02 MAY 2021 12:01:01
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 243

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 250

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 264

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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

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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUN 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

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

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 285

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 292

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 299

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 313

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 320

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 327

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3232157**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 334

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 341

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 13 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 17 AUG 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 348

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 20 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 24 AUG 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

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

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**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

**US3232157**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 376

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 383

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3232157**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 SEP 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 01 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 05 OCT 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 397

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

Date and time of submission

<a href="#">Patient Cloud Open Date &amp; Time</a>	08 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2021 23:59



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 404

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3232157**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 411

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

Date and time of submission

<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 418

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 425

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 432

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 439

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 446

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3232157**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 453

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 07 DEC 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 460

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 10 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 14 DEC 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 481

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 488

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 495

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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

**US3232157**

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

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**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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15 FEB 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 530

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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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

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Date and time of submission

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18 FEB 2022 00:01

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22 FEB 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

**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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

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01 MAR 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

**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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

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

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**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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11 MAR 2022 00:01

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15 MAR 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

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22 MAR 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

US3232157

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

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**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

**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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 APR 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

US3232157

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

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**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 APR 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

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

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**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 600

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 607

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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10 MAY 2022 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 614

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 621

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

**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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

**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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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

US3232157

**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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

**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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 649

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

**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

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[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

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

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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

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

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**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 15 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#) 19 JUL 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 691

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

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

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**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

**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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 12 AUG 2022 00:01

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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23 AUG 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

**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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 AUG 2022 00:01

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30 AUG 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 726

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

**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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02 SEP 2022 00:01

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06 SEP 2022 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 733

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

**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

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Date and time of submission

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09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 740

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

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Date and time of submission

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16 SEP 2022 00:01

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20 SEP 2022 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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

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

US3232157

**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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

US3232157

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

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04 OCT 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3232157

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

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**Generated On: 09 Jun 2021 16:11:01**

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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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

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US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 768

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

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18 OCT 2022 23:59

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 775

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

---

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

---

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59

---

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 782

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

---

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

---

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

---

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**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°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

US3232157

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

---

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

---

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

---



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3232157**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

---

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

---

US3232157

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:11:01

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		28 FEB 2021 18:05:01

US3232157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:51:46

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3232157

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:51:46

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:15:56

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3232157

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:15:56

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:15:56

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---



US3232157

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:15:56

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:15:56

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 04 MAR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3232157

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:15:56

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 16:01:24

Generated On: 09 Jun 2021 16:11:01

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 12 APR 2021

---

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

---

Folder OID VISIT4

---

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 16:01:24

Generated On: 09 Jun 2021 16:11:01

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) \_\_\_\_\_

US3232157

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

---

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.*

---

US3232157

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

Was the sample collected? Yes   
No

Collection date (*dd MMM yyyy*) \_\_\_\_\_

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

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

US3232157

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3232157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 15:23:45

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 APR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3232157

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 15:23:45

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

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* \_\_\_\_\_

US3232157

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Date of Contact	08 JAN 2021
Time of Contact	09:00
Date and Time of Contact (derived)	08 JAN 2021 09:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/> Clinical Visit - Unscheduled <input type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

Symptom Day

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

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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	06 JAN 2021
------	-------------

---

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

---

O2 Saturation	ND - Not Done
---------------	---------------

---

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

---

Temperature	ND - Not Done
-------------	---------------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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"/>



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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	07 JAN 2021
------	-------------

---

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 type="checkbox"/>
	Mild	<input checked="" 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"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 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"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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	08 JAN 2021
------	-------------

---

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

---

O2 Saturation	95 %
---------------	------

---

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

---

Temperature	98.3 F
-------------	--------

---

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 type="checkbox"/>
	Mild	<input checked="" 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"/>

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 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 (3)

Data signed: (b) (4) 02 Apr 2021 14:15:54

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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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 09 JAN 2021

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature 99.2 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

O2 Saturation	92 %
---------------	------

---

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

---

Temperature	98.6 F
-------------	--------

---

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

---

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

---

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

---

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

---

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EAB) (1725)

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Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input 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 type="radio"/>
	Severe <input checked="" 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 08 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 JAN 2021

Assessment Not Done False

O2 Saturation 98 %

O2 Saturation Units %

Temperature 98.6 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input 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 08 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

O2 Saturation	94 %
---------------	------

---

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

---

Temperature	98.2 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 JAN 2021

Assessment Not Done False

O2 Saturation 95 %

O2 Saturation Units %

Temperature 98.0 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input 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 type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 JAN 2021

Assessment Not Done False

O2 Saturation 97 %

O2 Saturation Units %

Temperature 97.6 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input 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 type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 JAN 2021

Assessment Not Done False

O2 Saturation 96 %

O2 Saturation Units %

Temperature 98.6 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input 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 type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

Symptom Day

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 JAN 2021

Assessment Not Done False

O2 Saturation 98 %

O2 Saturation Units %

Temperature 99.4 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	99.0 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 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 type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 JAN 2021

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 98.0 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 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 type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

O2 Saturation	100 %
---------------	-------

---

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

---

Temperature	97.7 F
-------------	--------

---

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

---

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

---

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

---

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

---

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

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---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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 (16)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

O2 Saturation	100 %
---------------	-------

---

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

---

Temperature	97.9 F
-------------	--------

---

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

---

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

---

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

---

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

---

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 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 type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 02 Apr 2021 14:15:54

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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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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 (17)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	96.7 F
-------------	--------

---

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

---

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

---

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

---

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

---

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 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 type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 02 Apr 2021 14:15:54

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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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

Symptom Day

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

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	99.5 F
-------------	--------

---

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

---

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

---

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

---

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

---

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---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

O2 Saturation	95 %
---------------	------

---

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

---

Temperature	98.3 F
-------------	--------

---

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

---

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

---

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

---

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

---

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EAB) (1725)

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Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

	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 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 type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.9 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

Symptom Day

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

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.5 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003 EAB) (1725)	410 of 4146
--	-------------

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.7 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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"/>

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.5 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

Symptom Day

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

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

	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 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.7 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

Date of Visit 08 JAN 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes   
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes   
No

Date of Test 08 JAN 2021

Type of Test Performed Nasopharyngeal Swab   
Nasal Swab   
Saliva Test   
Other

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

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes   
No

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes   
No

COVID-19 Positive (CSA Programming Field Only) 1

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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 10 JAN 2021

End Date 10 JAN 2021

Oxygen Saturation 92 %

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 \_\_\_\_\_

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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 \_\_\_\_\_

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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 \_\_\_\_\_

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

[Generate Next COVID-19 Assessment](#)

Yes

No

---

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	10 JAN 2021
Day 5	Yes	12 JAN 2021
Day 7	Yes	14 JAN 2021
Day 9	Yes	16 JAN 2021
Day 14	Yes	21 JAN 2021
Day 21	Yes	28 JAN 2021
Day 28	Yes	05 FEB 2021

US3232157

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 08 JAN 2021

---

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

---

Folder OID SICKD1

---



US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	08 JAN 2021
Time of assessment ( <i>00:00-23:59</i> )	09:17 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 09:17
Height ( <i>xxx.x</i> )	179 cm
Weight ( <i>xxx.x</i> )	80.29 kg
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	64 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3232157

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

08 JAN 2021

---

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

---

US3232157

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

---

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

08 JAN 2021

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

---

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	05 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	08:30 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 08:30
Height ( <i>xxx.x</i> )	178 cm
Weight ( <i>xxx.x</i> )	76.9 kg
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	64 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

05 FEB 2021

---

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

---

US3232157

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

---

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

05 FEB 2021

US3232157

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 11 FEB 2021

---

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

---

Folder OID UNBLND\_DECIDE

---



US3232157

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

Date of updated informed consent ( <i>dd MMM yyyy</i> )	11 FEB 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> )	11 FEB 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 checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3232157

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

---

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

---

---

US3232157

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	08:41 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 08:41
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3232157

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	09:27 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 09:27
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3232157

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

11 FEB 2021

---

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

---

US3232157

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

Was study treatment given? Yes   
No

If No, reason not given

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

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 09:15 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 09:15

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

What was the frequency of the study treatment dosing? ONCE

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

US3232157

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 11 FEB 2021

---

Collection time (*00:00-23:59*) 08:48 (24 HR)

---

Collection date and time (derived) 11 FEB 2021 08:48

---

US3232157

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 11 FEB 2021

---

Collection time (*00:00 - 23:59*) 08:43

---

Collection Date and Time (derived) 11 FEB 2021 08:43

---



US3232157

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:15:56

Generated On: 09 Jun 2021 16:11:01

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3232157

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:15:56

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

---

US3232157

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 16 MAR 2021

---

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

---

Folder OID OLD29

---

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

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

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

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

US3232157

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

---

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.*

---

US3232157

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

Was study treatment given? Yes   
No

If No, reason not given

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

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

What was the study treatment? (Unblinded) \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_



US3232157

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 15:23:45

Generated On: 09 Jun 2021 16:11:01

---

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

CALL NOT COMPLETED,  
PATIENT REQUESTED DUE TO  
HEALTH REASONS

---

*If Contact Not Made, please provide Comments*

---

US3232157

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3232157

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 12 APR 2021

---

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

---

Folder OID OLD57

---

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

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) \_\_\_\_\_

US3232157

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

---

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.*

---

US3232157

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

Was the sample collected?

Yes

No

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3232157

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 19:57:21

Generated On: 09 Jun 2021 16:11:01

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---



US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

AEID	USA-US105-2021-MRNA-1273-P30 1000001
Adverse event	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)	06 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)	05 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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

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

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	NEW ONSET GASTROENTERITIS
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)	10 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	_____

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	COUGH
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)	06 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)	05 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

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 _____	
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)	_____

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	TRANSAMINITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 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)	13 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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)	_____



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	WORSENING GASTROESOPHAGEAL REFLUX DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 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)	13 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
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	EGD 12MAR2021
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 (6)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	EARLY SATIETY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 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)	13 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

AEID

Adverse event

BILIARY OBSTRUCTION

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

12 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

13 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 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)	13 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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)	_____



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

AEID

Adverse event

PANCREATIC MASS  
(MALIGNANT/CANCEROUS)

Was this a medically-attended AE?

Yes

No

Was this a Solicited Adverse Reaction?

Yes

No

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

Yes

No

Start date (dd MMM yyyy)

26 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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 (10)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	FEVER
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)	11 MAR 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)	13 MAR 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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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 (11)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	CHOLANGITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 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)	13 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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)	_____

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	ABDOMINAL PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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 (13)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	INSOMNIA
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)	11 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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 (14)

Generated On: 09 Jun 2021 16:11:01

AEID USA-US105-2021-MRNA-1273-P30  
1000008

Adverse event METASTATIC PANCREATIC  
CANCER

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 22 MAR 2021

Start time (00:00-23:59) \_\_\_\_\_

AE start date and time (derived) \_\_\_\_\_

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) \_\_\_\_\_

End time (00:00-23:59) \_\_\_\_\_

AE End Date and Time (derived) \_\_\_\_\_

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy) \_\_\_\_\_

Hospital Discharge Date (dd MMM yyyy) \_\_\_\_\_

Admitted to ICU? Yes   
No   
Unknown

Number of Days in ICU \_\_\_\_\_

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Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

Persistent or significant disability or incapacity  False

Congenital anomaly or birth defect  False

Other medically important event  True

Relationship to investigational product  Not Related  
 Related  
 Not Applicable

Relationship to Study Procedure  Not Related  
 Related  
 Not Applicable

Action taken with investigational product  None  
 Dose Delayed  
 Investigational Product  
 Withdrawn  
 Not Applicable

Other action taken (check all that apply)

None  False

Concomitant Medication  True

Concomitant Procedure  True

Outcome  Fatal  
 Not Recovered/Not Resolved  
 Recovered/Resolved  
 Recovered/Resolved with Sequelae  
 Recovering/Resolving  
 Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative \_\_\_\_\_

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

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SUBJECT IS A 63 YEAR OLD  
MALE WHO RECEIVED HIS  
FIRST AND ONLY DOSE OF THE  
MRNA-1273-P301 TRIAL  
VACCINE ON 11 FEB 2021 AND  
WAS ULTIMATELY DIAGNOSED  
WITH METASTATIC  
PANCREATIC  
ADENOCARCINOMA WITH  
PERITONEAL IMPLANTS AND  
POSSIBLE PULMONARY  
METASTASES ON 30 MAR 2021.

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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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US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	PULMONARY INFILTRATES
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)	08 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)	13 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

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 _____	
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)	_____

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	NAUSEA
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)	30 MAR 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)	20 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

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	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)	_____

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	VOMITING
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 MAR 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)	20 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

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	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)	_____

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	CACHEXIA
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 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	_____

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	WEAKNESS
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 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	_____

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

AEID	
Adverse event	FATIGUE
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 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	_____

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:15:54

Generated On: 09 Jun 2021 16:11:01

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

Yes

No

---

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

---

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication CARDIAC PROPHYLACTIC

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 \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

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 2000

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication ATORVASTATIN

Prophylaxis Yes   
No

Indication HYPERLIPIDEMIA

Dose per administration 40

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

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 2000

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication PANTOPRAZOLE

Prophylaxis Yes   
No

Indication GERD

Dose per administration 40

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication FAMOTIDINE

Prophylaxis Yes   
No

Indication REFLUX

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

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   
No

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication VALOCYCLOVIR

Prophylaxis Yes   
No

Indication HERPES SIMPLEX VIRUS 2  
(FACE)

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

	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) 05 APR 2019

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication ZINC

Prophylaxis Yes   
No

Indication COVID-19

Dose per administration 100

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

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*) 08 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 22 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication AZITHROMYCIN

Prophylaxis Yes   
No

Indication COVID-19

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

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*) 08 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 08 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication AZITHROMYCINN

Prophylaxis Yes   
No

Indication COVID-19

Dose per administration 250

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

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*) 08 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 12 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication VITAMIN D3

Prophylaxis Yes   
No

Indication COVID-19

Dose per administration 200

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

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*) 08 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 22 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication VITAMIN C

Prophylaxis Yes   
No

Indication COVID-19

Dose per administration 1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 08 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 22 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication MEALTONIN

Prophylaxis Yes   
No

Indication COVID-19

Dose per administration 5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

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*) 08 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 22 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication IB GUARD

Prophylaxis Yes   
No

Indication GASTROENTERITIS

Dose per administration 2

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

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*) 15 FEB 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication GAS X

Prophylaxis Yes   
No

Indication GASTROENTERITIS

Dose per administration 2

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

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*) 15 FEB 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication FLAGYL

Prophylaxis Yes   
No

Indication SEPSIS/CHOLANGITIS

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

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*) 13 MAR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 23 MAR 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 3

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication ZOFRAN

Prophylaxis Yes   
No

Indication NAUSEA SECONDARY TO  
WORSENING  
GASTROESOPHAGEAL REFLUX  
DISEASE

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 13 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication PHENERGAN

Prophylaxis Yes   
No

Indication NAUSEA SECONDARY TO  
WORSENING  
GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 25

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 13 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication BUDESONIDE

Prophylaxis Yes   
No

Indication PULMONARY INFILTRATES

Dose per administration 90

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input checked="" 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*) 08 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication DICYCLOMINE

Prophylaxis Yes   
No

Indication GASTRIC EMPTYING  
SECONDARY TO CHOLANGITIS

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

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

	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) 08 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

---

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication FENTANYL

Prophylaxis Yes   
No

Indication ABDOMINAL PAIN  
(PANCREATIC MASS)

Dose per administration 144

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

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) 11 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

---



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication REGLAN

Prophylaxis Yes   
No

Indication GASTRIC EMPYTING  
SECONDARY TO CHOLANGITIS

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

	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) 11 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

---

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication REMERON (MIRTAZAPINE)

Prophylaxis Yes   
No

Indication INSOMNIA

Dose per administration 15

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

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*) 11 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication ULTRAM

Prophylaxis Yes   
No

Indication ABDOMINAL PAIN

Dose per administration 50

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

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*) 11 MAR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 11 MAR 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication TYLENOL

Prophylaxis Yes   
No

Indication FEVER

Dose per administration 1000

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 12 MAR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 12 MAR 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication NORMAL SALINE (SODIUM CHLORIDE)

Prophylaxis Yes   
No

Indication FLUID RESUSCITATION  
SECONDARY TO  
DEHYDRATION

Dose per administration 1000

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 12 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 13 MAR 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication PIPERACILLIN-TAZOBACTOBA  
M

Prophylaxis Yes   
No

Indication CHOLANGITIS/SEPSIS

Dose per administration 3.375

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	12 MAR 2021
--------------------------	-------------

---

Start date completely unknown	False
-------------------------------	-------

---

Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

---

If not Ongoing, End date (dd MMM yyyy)	13 MAR 2021
--	-------------

---

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

---

Separate Dosage Number (derived)	3
----------------------------------	---

---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

---

Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

---

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication LOVENOX

Prophylaxis Yes   
No

Indication PROPHYLACTIC CARDIAC

Dose per administration 40

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 12 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 13 MAR 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication MORPHINE

Prophylaxis Yes   
No

Indication ABDOMINAL PAIN

Dose per administration 2

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 12 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 13 MAR 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication PHENERGAN

Prophylaxis Yes   
No

Indication NAUSEA SECONDARY TO  
WORSENING  
GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 12.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 12 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 13 MAR 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication XYLOCAINE-MPF 2%

Prophylaxis Yes   
No

Indication PRE-OP EGD

Dose per administration 80

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 12 MAR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 12 MAR 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication DIPRIVAN

Prophylaxis Yes   
No

Indication ANESTHESIA EGD SECONDARY  
TO ABDOMINAL PAIN

Dose per administration 50

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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) 12 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 12 MAR 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication LEVAQUIN

Prophylaxis Yes   
No

Indication CHOLANGITIS/SEPSIS

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

566 of 4146

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

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*) 13 MAR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 23 MAR 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication ALEVE

Prophylaxis Yes   
No

Indication ABDOMINAL PAIN

Dose per administration 220

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

568 of 4146

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 25 FEB 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 10 MAR 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

---

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

Name of Medication 5-FU

Prophylaxis Yes   
No

Indication METASTATIC PANCREATIC  
ADENOCARCINOMA

Dose per administration 2400

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

CONTINUOUS INFUSION

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

570 of 4146

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 16:01:21

Generated On: 09 Jun 2021 16:11:01

---

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 30 MAR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 16:23:32

Generated On: 09 Jun 2021 16:11:01

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 15:23:45

Generated On: 09 Jun 2021 16:11:01

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 MAR 2021	ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPH Y	Adverse Event	
12 MAR 2021	ESOPHAGOGASTRODUODENOSC OPY	Adverse Event	
25 MAR 2021	LAPAROSCOPIC BIOPSY OF PERITONEAL AND OMENTAL MASSES WITH FROZEN SECTION AND INFUSAPORT PLACEMENT	Adverse Event	

US3232157

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Apr 2021 16:01:22

Generated On: 09 Jun 2021 16:11:01

---

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

---

US3232157

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:11:01

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



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

SAEID	USA-US105-2021-MRNA-1273-P301000001
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	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

SAEID USA-US105-2021-MRNA-1273-P30  
1000001

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name RAMBOD

Investigator's Last Name ROUHBAKHSH

Site Address: Street MEDISYNC CLINICAL  
RESEARCH HATTIESBURG  
CLINIC

Site Address: City PETAL

Site Address: State MS

Site Address: Postal Code 39465

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 2

Date of submission (Pre-filled from custom function) 12/JAN/2021 16:41

**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

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 14:15:55

Generated On: 09 Jun 2021 16:11:01

SAEID USA-US105-2021-MRNA-1273-P30  
1000001

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name RAMBOD

Investigator's Last Name ROUHBAKHSH

Site Address: Street MEDISYNC CLINICAL  
RESEARCH HATTIESBURG  
CLINIC

Site Address: City PETAL

Site Address: State MS

Site Address: Postal Code 39465

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 2

Date of submission (Pre-filled from custom function) 02/FEB/2021 16:44

**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

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 17:43:22

Generated On: 09 Jun 2021 16:11:01

SAEID	USA-US105-2021-MRNA-1273-P301000008
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 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 17:43:22

Generated On: 09 Jun 2021 16:11:01

SAEID	USA-US105-2021-MRNA-1273-P301000008
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 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RAMBOD
Investigator's Last Name	ROUHBAKHSH
Site Address: Street	MEDISYNC CLINICAL RESEARCH HATTIESBURG CLINIC
Site Address: City	PETAL
Site Address: State	MS
Site Address: Postal Code	39465
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/APR/2021 17:27
<b>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.</b>	True

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 17:43:22

Generated On: 09 Jun 2021 16:11:01

SAEID USA-US105-2021-MRNA-1273-P30  
1000008

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name RAMBOD

Investigator's Last Name ROUHBAKHSH

Site Address: Street MEDISYNC CLINICAL  
RESEARCH HATTIESBURG  
CLINIC

Site Address: City PETAL

Site Address: State MS

Site Address: Postal Code 39465

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 5

Date of submission (Pre-filled from custom function) 12/APR/2021 09:25

**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

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 17:43:22

Generated On: 09 Jun 2021 16:11:01

SAEID USA-US105-2021-MRNA-1273-P30  
1000008

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name RAMBOD

Investigator's Last Name ROUHBAKHSH

Site Address: Street MEDISYNC CLINICAL  
RESEARCH HATTIESBURG  
CLINIC

Site Address: City PETAL

Site Address: State MS

Site Address: Postal Code 39465

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 5

Date of submission (Pre-filled from custom function) 19/APR/2021 10:28

**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

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 17:43:22

Generated On: 09 Jun 2021 16:11:01

SAEID USA-US105-2021-MRNA-1273-P30  
1000008

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

Investigator's First Name RAMBOD

Investigator's Last Name ROUHBAKHSH

Site Address: Street MEDISYNC CLINICAL  
RESEARCH HATTIESBURG  
CLINIC

Site Address: City PETAL

Site Address: State MS

Site Address: Postal Code 39465

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 5

Date of submission (Pre-filled from custom function) 27/APR/2021 15:44

**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

US3232157 (Prod: MediSync Clinical Research Hattiesburg Clinic)

US3232157

Form: Participant Creation

Generated On: 09 Jun 2021 16:11:01

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'US3232157'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 18:14:32

US3232157

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:46:44

US3232157

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 18:14:33

US3232157

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[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 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Clinic (Clinic)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:46:44

US3232157

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'SCRN'	(b) (4), (b) (6) System	09 Sep 2020 21:46:44

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 18:14:34

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '62'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11



US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'YEARS'	(b) (4), (b) (6) System	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '62'	(b) (4), (b) (6) System	09 Sep 2020 19:24:25

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Male (M)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:47:11
	(b) (4)	

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '1'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11



US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:01

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:11

US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '9 Sep 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:24:25

US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Sep 2020'	(b) (4), (b) (6) System	09 Sep 2020 19:24:25

US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2020'	(b) (4), (b) (6) System	09 Sep 2020 19:24:25



US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Amendment 3 (3)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:24:25

US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 19:24:25
	(b) (4)	

US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:24:25

US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:24:25

US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:24:25

US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 18:14:33

US3232157

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '1'	(b) (4), (b) (6) System	09 Sep 2020 19:24:29

US3232157

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:24:29



US3232157

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:11:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:47:39

US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Surgical and medical procedures, HLT: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Vision correction operation, LLT: Vision correction operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Sep 2020 21:49:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:49:43
Data point term sent to Coder	System	09 Sep 2020 21:49:00
User entered 'Laser Vision Correction'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:48:50

US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 2005'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:48:50

US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:48:50

US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:48:50

US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 2005'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:48:50

US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:48:50

US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 2005'	(b) (4), (b) (6) System	09 Sep 2020 21:48:50



US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2005'	(b) (4), (b) (6) System	09 Sep 2020 21:48:50

US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 2005'	(b) (4), (b) (6) System	09 Sep 2020 21:48:50

US3232157

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2005'	(b) (4), (b) (6) System	09 Sep 2020 21:48:50

US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Sep 2020 21:50:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:50:58
Data point term sent to Coder	System	09 Sep 2020 21:50:01
User entered 'Cataracts'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:20

US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 2019'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:20

US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:20

US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:20

US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 2019'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:20



US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:20

US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 2019'	(b) (4), (b) (6) System	09 Sep 2020 21:49:20

US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2019'	(b) (4), (b) (6) System	09 Sep 2020 21:49:20

US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 2019'	(b) (4), (b) (6) System	09 Sep 2020 21:49:20

US3232157

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2019'	(b) (4), (b) (6) System	09 Sep 2020 21:49:20

US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 21:50:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:50:46
Data point term sent to Coder	System	09 Sep 2020 21:50:03
User entered 'sleep apnea'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:40

US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 2018'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:40

US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:40



US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:40

US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:40

US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:49:40

US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 2018'	(b) (4), (b) (6) System	09 Sep 2020 21:49:40

US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2018'	(b) (4), (b) (6) System	09 Sep 2020 21:49:40

US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:49:40

US3232157

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:49:40

US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 21:51:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:51:43
Data point term sent to Coder	System	09 Sep 2020 21:51:07
User entered 'hyperlipidemia'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:50:27



US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 2000'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:50:27

US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:50:27

US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	09 Sep 2020 21:50:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:50:41
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	09 Sep 2020 21:50:27
User entered 'No (N)'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:50:27

US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:50:27
	(b) (4)	

US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:50:27

US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 2000'	(b) (4), (b) (6) System	09 Sep 2020 21:50:27

US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2000'	(b) (4), (b) (6) System	09 Sep 2020 21:50:27

US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:50:27



US3232157

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:50:27

US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 21:54:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:54:46
Data point term sent to Coder	System	09 Sep 2020 21:54:12
User entered 'Gastroesophageal reflux disease'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:53:33

US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 2018'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:53:33

US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:53:33

US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:53:33

US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:53:33
	(b) (4)	

US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:53:33

US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 2018'	(b) (4), (b) (6) System	09 Sep 2020 21:53:33



US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2018'	(b) (4), (b) (6) System	09 Sep 2020 21:53:33

US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:53:33

US3232157

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:53:33

US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Nervous system disorders, HLGHT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 21:54:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:54:46
Data point term sent to Coder	System	09 Sep 2020 21:54:13
User entered 'migraine headaches'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:00

US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 1980'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:00

US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:00

US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:00

US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:00



US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:00

US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 1980'	(b) (4), (b) (6) System	09 Sep 2020 21:54:00

US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '1980'	(b) (4), (b) (6) System	09 Sep 2020 21:54:00

US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:54:00

US3232157

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:54:00

US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Social issues NEC, PT: Blood donor, LLT: Blood donor - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 21:55:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:55:47
Data point term sent to Coder	System	09 Sep 2020 21:55:15
User entered 'frequent blood donor'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:37

US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '15 Mar 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:37

US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:37



US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:37

US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '15 Mar 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:37

US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:54:37

US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Mar 2020'	(b) (4), (b) (6) System	09 Sep 2020 21:54:37

US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2020'	(b) (4), (b) (6) System	09 Sep 2020 21:54:37

US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Mar 2020'	(b) (4), (b) (6) System	09 Sep 2020 21:54:37

US3232157

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2020'	(b) (4), (b) (6) System	09 Sep 2020 21:54:37

US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Sep 2020 21:57:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:57:50
Data point term sent to Coder	System	09 Sep 2020 21:56:16
User entered 'osteoarthritis'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:55:37



US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 2016'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:55:37

US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:55:37

US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:55:37

US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:55:37

US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:55:37

US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 2016'	(b) (4), (b) (6) System	09 Sep 2020 21:55:37

US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2016'	(b) (4), (b) (6) System	09 Sep 2020 21:55:37

US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:55:37



US3232157

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:55:37

US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	09 Sep 2020 21:57:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:57:50
Data point term sent to Coder	System	09 Sep 2020 21:56:17
User entered 'recurrent back pain'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:11

US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 2016'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:11

US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:11

US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:11

US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:56:11
	(b) (4)	

US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:11

US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 2016'	(b) (4), (b) (6) System	09 Sep 2020 21:56:11



US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2016'	(b) (4), (b) (6) System	09 Sep 2020 21:56:11

US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:56:11

US3232157

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 21:56:11

US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Head, neck and oral cavity therapeutic procedures NEC, PT: Neck surgery, LLT: Neck surgery - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	09 Sep 2020 21:58:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 21:58:51
Data point term sent to Coder	System	09 Sep 2020 21:57:19
User entered 'cervical surgery'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:54

US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 1998'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:54

US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:54

US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:54

US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'un UNK 1998'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:54



US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:56:54

US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 1998'	(b) (4), (b) (6) System	09 Sep 2020 21:56:54

US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '1998'	(b) (4), (b) (6) System	09 Sep 2020 21:56:54

US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Jan 1998'	(b) (4), (b) (6) System	09 Sep 2020 21:56:54

US3232157

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '1998'	(b) (4), (b) (6) System	09 Sep 2020 21:56:54

US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type II - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Nov 2020 05:17:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 05:17:36
Data point term sent to Coder	System	04 Nov 2020 21:09:35
User entered 'herpes simplex virus 2 (face)'	Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:09:06

US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '29 Aug 2013'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:09:06

US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:09:06



US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	04 Nov 2020 21:09:06
	(b) (4)	

US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	04 Nov 2020 21:09:06
	(b) (4)	

US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:09:06

US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'Aug 2013'	(b) (4), (b) (6) System	04 Nov 2020 21:09:06

US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '2013'	(b) (4), (b) (6) System	04 Nov 2020 21:09:06

US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	04 Nov 2020 21:09:06

US3232157

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6) System	04 Nov 2020 21:09:06

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:58:52



US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '9 Sep 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '13:35'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '9 Sep 2020 13:35'	(b) (4), (b) (6) System	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '179' cm	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:58:52
DataPoint set to visible.	(b) (4) System	09 Sep 2020 19:24:29

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '80.7' kg	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:58:52
DataPoint set to visible.	(b) (4) System	09 Sep 2020 19:24:29

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '25.18648'	(b) (4), (b) (6)	09 Sep 2020 21:58:52
DataPoint set to visible.	System	09 Sep 2020 19:24:29

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'kg/m2'	(b) (4), (b) (6)	09 Sep 2020 21:58:52
DataPoint set to visible.	System	09 Sep 2020 19:24:29

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:58:52
	(b) (4)	



US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:58:52
	(b) (4)	

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'bpm'	(b) (4), (b) (6) System	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:58:52
	(b) (4)	

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'mmHg'	(b) (4), (b) (6) System	09 Sep 2020 21:58:52



US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'mmHg'	(b) (4), (b) (6) System	09 Sep 2020 21:58:52

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:19:55

US3232157

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 09:19:55

US3232157

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 21:59:31
	(b) (4)	

US3232157

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '9 Sep 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:59:31

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28



US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28



US3232157

Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28



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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '1'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'resident in a community with ongoing person to person transmission'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:00:28

US3232157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:46:06

US3232157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '9 Sep 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:46:06

US3232157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Clinic (Clinic)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 21:46:06

US3232157

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'VISIT1'	(b) (4), (b) (6) System	09 Sep 2020 21:46:06

US3232157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 19:04:48



US3232157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:01

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '111003'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 19:04:48

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:01

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Sep 2020 19:04:48

US3232157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:01

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)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:01:13

US3232157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:01

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)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:01:13

US3232157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:01

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:01:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:01:13

US3232157

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:01

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:01:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:01

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4)	01 Dec 2020 19:13:17
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:51:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:51:35



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Adreanna Pou (b) (4)	09 Sep 2020 22:04:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '9 Sep 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '13:35'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '9 Sep 2020 13:35'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '98' F	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Oral (Oral)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '46'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'bpm'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '20'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '122'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '74'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered missing code ND - Not Done.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '9 Sep 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '14:40'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '9 Sep 2020 14:40'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '97.3' F	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Other (Other)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'temporal'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '65'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'bpm'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42



US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '20'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'breaths/min'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '125'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '80'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	09 Sep 2020 22:04:42

US3232157

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:48

US3232157

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:04:48



US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:25:04

US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:25:04

US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

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 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:25:04

US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '9 Sep 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:25:04

US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '14:20'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:25:04

US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '9 Sep 2020 14:20'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 19:25:04



US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'ONCE'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:05:10

US3232157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '9 Sep 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:05:10

US3232157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '14:10'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:05:10

US3232157

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '9 Sep 2020 14:10'	(b) (4), (b) (6) System	09 Sep 2020 22:05:10

US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:11:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '9 Sep 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:05:47

US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Adreanna Pou (b) (4)	09 Sep 2020 22:05:47
	(b) (4)	



US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:05:47

US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '13:45'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:05:47

US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '9 Sep 2020 13:45'	(b) (4), (b) (6) System	09 Sep 2020 22:05:47

US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Adreanna Pou (b) (4)	09 Sep 2020 22:05:47
	(b) (4)	

US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:05:47

US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:05:47

US3232157

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered empty.	(b) (4), (b) (6) System	09 Sep 2020 22:05:47

US3232157

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:05:50



US3232157

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '1'	(b) (4), (b) (6) System	09 Sep 2020 22:05:50

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59



US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Sep 2020 14:40'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Sep 2020 17:10'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T18:58:04', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '4fc9995c-3a48-4633-8970-d402a6e1de4f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	09 Sep 2020 23:58:39
	System	09 Sep 2020 23:58:39

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T18:58:17', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '4fc9995c-3a48-4633-8970-d402a6e1de4f' User entered '97.9'	System	09 Sep 2020 23:58:39
	System	09 Sep 2020 23:58:39

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T18:58:21', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '4fc9995c-3a48-4633-8970-d402a6e1de4f' User entered 'No (N)'	System	09 Sep 2020 23:58:39
	System	09 Sep 2020 23:58:39

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T18:58:36', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '4fc9995c-3a48-4633-8970-d402a6e1de4f' User entered '09 Sep 2020 18:58'	(b) (4), (b) (6) System	09 Sep 2020 23:58:39
	System	09 Sep 2020 23:58:39

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Sep 2020 18:05'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04



US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 2'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:54:38', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3e9a5267-4181-46a0-b7d4-51c58e9eddc'	System	11 Sep 2020 00:54:59
User entered 'Yes (Y)'	System	11 Sep 2020 00:54:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:54:47', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3e9a5267-4181-46a0-b7d4-51c58e9eddc'	System	11 Sep 2020 00:54:59
User entered '97.1'	System	11 Sep 2020 00:54:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:54:51', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3e9a5267-4181-46a0-b7d4-51c58e9eddcc' User entered 'No (N)'	System	11 Sep 2020 00:54:59
	System	11 Sep 2020 00:54:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:54:56', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3e9a5267-4181-46a0-b7d4-51c58e9eddc'	(b) (4), (b) (6) System	11 Sep 2020 00:54:59
User entered '10 Sep 2020 19:54'	System	11 Sep 2020 00:54:59

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04



US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 3'	System	09 Sep 2020 19:25:04
	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:16:21', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '166e75b9-8926-4ead-bd97-6621677ee7a9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Sep 2020 22:16:48
	System	11 Sep 2020 22:16:48

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:16:29', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '166e75b9-8926-4ead-bd97-6621677ee7a9' User entered '97.5'	System	11 Sep 2020 22:16:48
	System	11 Sep 2020 22:16:48

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:16:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '166e75b9-8926-4ead-bd97-6621677ee7a9' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 22:16:48
	System	11 Sep 2020 22:16:48

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:16:42', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '166e75b9-8926-4ead-bd97-6621677ee7a9'	(b) (4), (b) (6) System	11 Sep 2020 22:16:48
User entered '11 Sep 2020 17:16'	System	11 Sep 2020 22:16:48

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 4'	System	09 Sep 2020 19:25:04



US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:00:09', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '010bb5af-2ee5-4206-8825-ee6e0b25bae9' User entered 'Yes (Y)'	System	13 Sep 2020 15:03:15
	System	13 Sep 2020 15:03:15

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:00:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '010bb5af-2ee5-4206-8825-ee6e0b25bae9' User entered '97.3'	System	13 Sep 2020 15:03:15
	System	13 Sep 2020 15:03:15

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:01:59', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '010bb5af-2ee5-4206-8825-ee6e0b25bae9' User entered 'No (N)'	System	13 Sep 2020 15:03:15
	System	13 Sep 2020 15:03:15

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:02:17', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '010bb5af-2ee5-4206-8825-ee6e0b25bae9' User entered '13 Sep 2020 10:02'	System	13 Sep 2020 15:03:15
	System	13 Sep 2020 15:03:15

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 5'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:58:38', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '246340fa-cfcc-4e58-9c3a-a1869e60cbc2' User entered 'Yes (Y)'	System	14 Sep 2020 02:58:56
	System	14 Sep 2020 02:58:56



US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:58:44', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '246340fa-cfcc-4e58-9c3a-a1869e60cbc2' User entered '97.5'	System	14 Sep 2020 02:58:56
	System	14 Sep 2020 02:58:56

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:58:48', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '246340fa-cfcc-4e58-9c3a-a1869e60cbc2' User entered 'No (N)'	System	14 Sep 2020 02:58:56
	System	14 Sep 2020 02:58:56

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:58:55', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '246340fa-cfcc-4e58-9c3a-a1869e60cbc2' User entered '13 Sep 2020 21:58'	System	14 Sep 2020 02:58:56
	System	14 Sep 2020 02:58:56

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 6'	System	09 Sep 2020 19:25:04
	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:13:54', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'ed062c9a-40cd-45de-8838-3c144c5b3bf0' User entered 'Yes (Y)'	System	15 Sep 2020 06:14:10
	System	15 Sep 2020 06:14:10

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'ed062c9a-40cd-45de-8838-3c144c5b3bf0' User entered '96.7'	System	15 Sep 2020 06:14:10
	System	15 Sep 2020 06:14:10



US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:04', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'ed062c9a-40cd-45de-8838-3c144c5b3bf0' User entered 'No (N)'	System	15 Sep 2020 06:14:10
	System	15 Sep 2020 06:14:10

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:07', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'ed062c9a-40cd-45de-8838-3c144c5b3bf0' User entered '15 Sep 2020 01:14'	System	15 Sep 2020 06:14:10
	System	15 Sep 2020 06:14:10

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 7'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:21:47', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1aa58386-82b9-43bd-9689-bc1d40a74cc4' User entered 'Yes (Y)'	(b) (4), (b) (6) System	16 Sep 2020 06:34:45
	System	16 Sep 2020 06:34:45

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:34:39', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1aa58386-82b9-43bd-9689-bc1d40a74cc4' User entered '97.3'	System	16 Sep 2020 06:34:45
	System	16 Sep 2020 06:34:45

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:34:04', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1aa58386-82b9-43bd-9689-bc1d40a74cc4' User entered 'No (N)'	System	16 Sep 2020 06:34:45
	System	16 Sep 2020 06:34:45



US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:34:42', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1aa58386-82b9-43bd-9689-bc1d40a74cc4' User entered '16 Sep 2020 01:34'	System	16 Sep 2020 06:34:45
	System	16 Sep 2020 06:34:45

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59



US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Sep 2020 14:40'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Sep 2020 17:10'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T18:59:21', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '20659b43-b001-4af4-b71d-d10bca6ffc48'	(b) (4), (b) (6) System	10 Sep 2020 00:01:15
User entered 'None (1)'	System	10 Sep 2020 00:01:15

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:00:45', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '20659b43-b001-4af4-b71d-d10bca6ffc48'	(b) (4), (b) (6) System	10 Sep 2020 00:01:15
User entered 'No (N)'	System	10 Sep 2020 00:01:15



US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:00:54', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '20659b43-b001-4af4-b71d-d10bca6ffc48'	(b) (4), (b) (6) System	10 Sep 2020 00:01:15
User entered 'No (N)'	System	10 Sep 2020 00:01:15

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:06', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '20659b43-b001-4af4-b71d-d10bca6ffc48'	(b) (4), (b) (6) System	10 Sep 2020 00:01:15
User entered 'None (1)'	System	10 Sep 2020 00:01:15

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:14', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '20659b43-b001-4af4-b71d-d10bca6ffc48' User entered '09 Sep 2020 19:01'	(b) (4), (b) (6) System	10 Sep 2020 00:01:15
	System	10 Sep 2020 00:01:15

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Sep 2020 18:05'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 2'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:01', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'fe78880a-0701-4347-93be-91d8b143db8a'	(b) (4), (b) (6) System	11 Sep 2020 00:55:28
User entered 'None (1)'	System	11 Sep 2020 00:55:28

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:04', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'fe78880a-0701-4347-93be-91d8b143db8a' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 00:55:28
	System	11 Sep 2020 00:55:28



US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:07', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'fe78880a-0701-4347-93be-91d8b143db8a' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 00:55:28
	System	11 Sep 2020 00:55:28

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:21', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'fe78880a-0701-4347-93be-91d8b143db8a'	(b) (4), (b) (6) System	11 Sep 2020 00:55:28
User entered 'None (1)'	System	11 Sep 2020 00:55:28

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:26', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'fe78880a-0701-4347-93be-91d8b143db8a' User entered '10 Sep 2020 19:55'	(b) (4), (b) (6) System	11 Sep 2020 00:55:28
	System	11 Sep 2020 00:55:28

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 3'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:16:46', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '01563736-3c28-431e-80aa-4a35045d5644'	(b) (4), (b) (6) System	11 Sep 2020 22:17:29
User entered 'None (1)'	System	11 Sep 2020 22:17:29

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:16:49', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '01563736-3c28-431e-80aa-4a35045d5644' User entered 'No (N)'	System	11 Sep 2020 22:17:29
	System	11 Sep 2020 22:17:29



US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:16:54', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '01563736-3c28-431e-80aa-4a35045d5644'	(b) (4), (b) (6) System	11 Sep 2020 22:17:29
User entered 'No (N)'	System	11 Sep 2020 22:17:29

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:05', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '01563736-3c28-431e-80aa-4a35045d5644'	(b) (4), (b) (6) System	11 Sep 2020 22:17:29
User entered 'None (1)'	System	11 Sep 2020 22:17:29

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:12', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '01563736-3c28-431e-80aa-4a35045d5644'	System	11 Sep 2020 22:17:29
User entered '11 Sep 2020 17:17'	System	11 Sep 2020 22:17:29

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 4'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:02:25', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'af3a235c-9df6-4726-8906-2a95ec0c2d86'	(b) (4), (b) (6) System	13 Sep 2020 15:05:09
User entered 'None (1)'	System	13 Sep 2020 15:05:09

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:02:36', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'af3a235c-9df6-4726-8906-2a95ec0c2d86'	(b) (4), (b) (6) System	13 Sep 2020 15:05:09
User entered 'No (N)'	System	13 Sep 2020 15:05:09



US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:02:43', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'af3a235c-9df6-4726-8906-2a95ec0c2d86'	System	13 Sep 2020 15:05:09
User entered 'No (N)'	System	13 Sep 2020 15:05:09

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:02', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'af3a235c-9df6-4726-8906-2a95ec0c2d86'	(b) (4), (b) (6) System	13 Sep 2020 15:05:09
User entered 'None (1)'	System	13 Sep 2020 15:05:09

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:06', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'af3a235c-9df6-4726-8906-2a95ec0c2d86' User entered '13 Sep 2020 10:05'	System	13 Sep 2020 15:05:09
	System	13 Sep 2020 15:05:09

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 5'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3d1201e7-fbc0-45ad-b9b3-f928517cbc7b' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 02:59:18
	System	14 Sep 2020 02:59:18

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:03', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3d1201e7-fbc0-45ad-b9b3-f928517cbc7b' User entered 'No (N)'	System	14 Sep 2020 02:59:18
	System	14 Sep 2020 02:59:18



US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:06', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3d1201e7-fbc0-45ad-b9b3-f928517cbc7b' User entered 'No (N)'	System	14 Sep 2020 02:59:18
	System	14 Sep 2020 02:59:18

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:12', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3d1201e7-fbc0-45ad-b9b3-f928517cbc7b' User entered 'None (1)'	(b) (4), (b) (6) System	14 Sep 2020 02:59:18
	System	14 Sep 2020 02:59:18

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:16', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3d1201e7-fbc0-45ad-b9b3-f928517cbc7b' User entered '13 Sep 2020 21:59'	System	14 Sep 2020 02:59:18
	System	14 Sep 2020 02:59:18

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 6'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:16', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7a3228b1-6a33-4ca4-87f6-c6e701efbf19'	(b) (4), (b) (6) System	15 Sep 2020 06:14:30
User entered 'None (1)'	System	15 Sep 2020 06:14:30

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7a3228b1-6a33-4ca4-87f6-c6e701efbf19' User entered 'No (N)'	System	15 Sep 2020 06:14:30
	System	15 Sep 2020 06:14:30



US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:23', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7a3228b1-6a33-4ca4-87f6-c6e701efbf19' User entered 'No (N)'	System	15 Sep 2020 06:14:30
	System	15 Sep 2020 06:14:30

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:25', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7a3228b1-6a33-4ca4-87f6-c6e701efbf19'	(b) (4), (b) (6) System	15 Sep 2020 06:14:30
User entered 'None (1)'	System	15 Sep 2020 06:14:30

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:28', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7a3228b1-6a33-4ca4-87f6-c6e701efbf19' User entered '15 Sep 2020 01:14'	System	15 Sep 2020 06:14:30
	System	15 Sep 2020 06:14:30

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 7'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:34:48', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '12ccced8-4811-4831-ba53-a7d3ab979df7'	(b) (4), (b) (6) System	16 Sep 2020 06:35:12
User entered 'None (1)'	System	16 Sep 2020 06:35:12

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:34:51', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '12ccced8-4811-4831-ba53-a7d3ab979df7' User entered 'No (N)'	System	16 Sep 2020 06:35:12
	System	16 Sep 2020 06:35:12



US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:34:55', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '12ccced8-4811-4831-ba53-a7d3ab979df7' User entered 'No (N)'	System	16 Sep 2020 06:35:12
	System	16 Sep 2020 06:35:12

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:06', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '12ccced8-4811-4831-ba53-a7d3ab979df7'	(b) (4), (b) (6) System	16 Sep 2020 06:35:12
User entered 'None (1)'	System	16 Sep 2020 06:35:12

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:09', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '12ccced8-4811-4831-ba53-a7d3ab979df7' User entered '16 Sep 2020 01:35'	System	16 Sep 2020 06:35:12
	System	16 Sep 2020 06:35:12

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

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) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Sep 2020 14:40'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Sep 2020 17:10'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:21', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bc1ca369-10b2-40aa-82bc-0bf315740e0f' User entered 'None (0)'	System	10 Sep 2020 00:01:47
	System	10 Sep 2020 00:01:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:24', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bc1ca369-10b2-40aa-82bc-0bf315740e0f' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 00:01:47
	System	10 Sep 2020 00:01:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:27', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bc1ca369-10b2-40aa-82bc-0bf315740e0f' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 00:01:47
	System	10 Sep 2020 00:01:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:29', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bc1ca369-10b2-40aa-82bc-0bf315740e0f' User entered 'None (0)'	(b) (4), (b) (6) System	10 Sep 2020 00:01:47
	System	10 Sep 2020 00:01:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:32', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bc1ca369-10b2-40aa-82bc-0bf315740e0f' User entered 'None (0)'	System	10 Sep 2020 00:01:47
	System	10 Sep 2020 00:01:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bc1ca369-10b2-40aa-82bc-0bf315740e0f' User entered 'None (0)'	System	10 Sep 2020 00:01:47
	System	10 Sep 2020 00:01:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:39', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bc1ca369-10b2-40aa-82bc-0bf315740e0f'	(b) (4), (b) (6) System	10 Sep 2020 00:01:47
User entered 'No (N)'	System	10 Sep 2020 00:01:47



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-09T19:01:44', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bc1ca369-10b2-40aa-82bc-0bf315740e0f' User entered '09 Sep 2020 19:01'	(b) (4), (b) (6) System	10 Sep 2020 00:01:47
	System	10 Sep 2020 00:01:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Sep 2020 18:05'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 2'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:31', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '95c00b8a-cb4f-4910-8aca-56fe603f8422'	System	11 Sep 2020 00:55:58
User entered 'None (0)'	System	11 Sep 2020 00:55:58

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '95c00b8a-cb4f-4910-8aca-56fe603f8422' User entered 'None (0)'	System	11 Sep 2020 00:55:58
	System	11 Sep 2020 00:55:58

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:37', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '95c00b8a-cb4f-4910-8aca-56fe603f8422'	System	11 Sep 2020 00:55:58
User entered 'None (0)'	System	11 Sep 2020 00:55:58

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:39', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '95c00b8a-cb4f-4910-8aca-56fe603f8422'	System	11 Sep 2020 00:55:58
User entered 'None (0)'	System	11 Sep 2020 00:55:58



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:41', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '95c00b8a-cb4f-4910-8aca-56fe603f8422' User entered 'None (0)'	System	11 Sep 2020 00:55:58
	System	11 Sep 2020 00:55:58

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:43', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '95c00b8a-cb4f-4910-8aca-56fe603f8422'	(b) (4), (b) (6) System	11 Sep 2020 00:55:58
User entered 'None (0)'	System	11 Sep 2020 00:55:58

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

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) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:47', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '95c00b8a-cb4f-4910-8aca-56fe603f8422'	System	11 Sep 2020 00:55:58
User entered 'No (N)'	System	11 Sep 2020 00:55:58

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-10T19:55:57', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '95c00b8a-cb4f-4910-8aca-56fe603f8422'	(b) (4), (b) (6) System	11 Sep 2020 00:55:58
User entered '10 Sep 2020 19:55'	System	11 Sep 2020 00:55:58

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 3'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:16', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9278e819-5fe9-4944-bc80-b668b6882acd' User entered 'None (0)'	System	11 Sep 2020 22:17:55
	System	11 Sep 2020 22:17:55



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9278e819-5fe9-4944-bc80-b668b6882acd' User entered 'None (0)'	(b) (4), (b) (6) System	11 Sep 2020 22:17:55
	System	11 Sep 2020 22:17:55

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:23', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9278e819-5fe9-4944-bc80-b668b6882acd' User entered 'None (0)'	System	11 Sep 2020 22:17:55
	System	11 Sep 2020 22:17:55

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:36', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9278e819-5fe9-4944-bc80-b668b6882acd' User entered 'None (0)'	System	11 Sep 2020 22:17:55
	System	11 Sep 2020 22:17:55

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:39', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9278e819-5fe9-4944-bc80-b668b6882acd' User entered 'None (0)'	System	11 Sep 2020 22:17:55
	System	11 Sep 2020 22:17:55

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:43', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9278e819-5fe9-4944-bc80-b668b6882acd' User entered 'None (0)'	System	11 Sep 2020 22:17:55
	System	11 Sep 2020 22:17:55

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:47', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9278e819-5fe9-4944-bc80-b668b6882acd' User entered 'No (N)'	(b) (4), (b) (6) System	11 Sep 2020 22:17:55
	System	11 Sep 2020 22:17:55

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-11T17:17:51', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9278e819-5fe9-4944-bc80-b668b6882acd' User entered '11 Sep 2020 17:17'	(b) (4), (b) (6) System	11 Sep 2020 22:17:55
	System	11 Sep 2020 22:17:55

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 4'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:12', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a77090d8-6753-4146-a5da-10a6256dc18d' User entered 'None (0)'	System	13 Sep 2020 15:05:42
	System	13 Sep 2020 15:05:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:14', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a77090d8-6753-4146-a5da-10a6256dc18d' User entered 'None (0)'	System	13 Sep 2020 15:05:42
	System	13 Sep 2020 15:05:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:17', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a77090d8-6753-4146-a5da-10a6256dc18d' User entered 'None (0)'	System	13 Sep 2020 15:05:42
	System	13 Sep 2020 15:05:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a77090d8-6753-4146-a5da-10a6256dc18d' User entered 'None (0)'	System	13 Sep 2020 15:05:42
	System	13 Sep 2020 15:05:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:22', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a77090d8-6753-4146-a5da-10a6256dc18d' User entered 'None (0)'	System	13 Sep 2020 15:05:42
	System	13 Sep 2020 15:05:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:25', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a77090d8-6753-4146-a5da-10a6256dc18d' User entered 'None (0)'	System	13 Sep 2020 15:05:42
	System	13 Sep 2020 15:05:42



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:31', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a77090d8-6753-4146-a5da-10a6256dc18d' User entered 'No (N)'	(b) (4), (b) (6) System	13 Sep 2020 15:05:42
	System	13 Sep 2020 15:05:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T10:05:35', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a77090d8-6753-4146-a5da-10a6256dc18d' User entered '13 Sep 2020 10:05'	(b) (4), (b) (6) System	13 Sep 2020 15:05:42
	System	13 Sep 2020 15:05:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 5'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:20', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d72bf34-6d7d-4c66-a00a-e05b6237a918' User entered 'None (0)'	System	14 Sep 2020 02:59:47
	System	14 Sep 2020 02:59:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:25', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d72bf34-6d7d-4c66-a00a-e05b6237a918' User entered 'None (0)'	System	14 Sep 2020 02:59:47
	System	14 Sep 2020 02:59:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:28', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d72bf34-6d7d-4c66-a00a-e05b6237a918' User entered 'None (0)'	(b) (4), (b) (6) System	14 Sep 2020 02:59:47
	System	14 Sep 2020 02:59:47



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:30', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d72bf34-6d7d-4c66-a00a-e05b6237a918' User entered 'None (0)'	System	14 Sep 2020 02:59:47
	System	14 Sep 2020 02:59:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d72bf34-6d7d-4c66-a00a-e05b6237a918' User entered 'None (0)'	System	14 Sep 2020 02:59:47
	System	14 Sep 2020 02:59:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:38', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d72bf34-6d7d-4c66-a00a-e05b6237a918' User entered 'None (0)'	System	14 Sep 2020 02:59:47
	System	14 Sep 2020 02:59:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

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) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:42', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d72bf34-6d7d-4c66-a00a-e05b6237a918' User entered 'No (N)'	System	14 Sep 2020 02:59:47
	System	14 Sep 2020 02:59:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-13T21:59:46', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d72bf34-6d7d-4c66-a00a-e05b6237a918' User entered '13 Sep 2020 21:59'	(b) (4), (b) (6) System	14 Sep 2020 02:59:47
	System	14 Sep 2020 02:59:47

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 6'	System	09 Sep 2020 19:25:04



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:31', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'dd39cb0a-86cb-4846-9d4a-75574fde75c3' User entered 'None (0)'	System	15 Sep 2020 06:14:51
	System	15 Sep 2020 06:14:51

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'dd39cb0a-86cb-4846-9d4a-75574fde75c3' User entered 'None (0)'	(b) (4), (b) (6) System	15 Sep 2020 06:14:51
	System	15 Sep 2020 06:14:51

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:36', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'dd39cb0a-86cb-4846-9d4a-75574fde75c3' User entered 'None (0)'	System	15 Sep 2020 06:14:51
	System	15 Sep 2020 06:14:51

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:38', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'dd39cb0a-86cb-4846-9d4a-75574fde75c3' User entered 'None (0)'	System	15 Sep 2020 06:14:51
	System	15 Sep 2020 06:14:51

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:40', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'dd39cb0a-86cb-4846-9d4a-75574fde75c3' User entered 'None (0)'	System	15 Sep 2020 06:14:51
	System	15 Sep 2020 06:14:51

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:42', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'dd39cb0a-86cb-4846-9d4a-75574fde75c3' User entered 'None (0)'	System	15 Sep 2020 06:14:51
	System	15 Sep 2020 06:14:51

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

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) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:46', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'dd39cb0a-86cb-4846-9d4a-75574fde75c3' User entered 'No (N)'	System	15 Sep 2020 06:14:51
	System	15 Sep 2020 06:14:51

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-15T01:14:49', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'dd39cb0a-86cb-4846-9d4a-75574fde75c3' User entered '15 Sep 2020 01:14'	System	15 Sep 2020 06:14:51
	System	15 Sep 2020 06:14:51



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 7'	System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:13', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6c5876ad-90c8-40ef-bbac-3a81a13701cb' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 06:35:42
	System	16 Sep 2020 06:35:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:16', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6c5876ad-90c8-40ef-bbac-3a81a13701cb' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 06:35:42
	System	16 Sep 2020 06:35:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6c5876ad-90c8-40ef-bbac-3a81a13701cb' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 06:35:42
	System	16 Sep 2020 06:35:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:23', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6c5876ad-90c8-40ef-bbac-3a81a13701cb' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 06:35:42
	System	16 Sep 2020 06:35:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:25', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6c5876ad-90c8-40ef-bbac-3a81a13701cb' User entered 'None (0)'	System	16 Sep 2020 06:35:42
	System	16 Sep 2020 06:35:42



US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:27', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6c5876ad-90c8-40ef-bbac-3a81a13701cb' User entered 'None (0)'	(b) (4), (b) (6) System	16 Sep 2020 06:35:42
	System	16 Sep 2020 06:35:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:30', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6c5876ad-90c8-40ef-bbac-3a81a13701cb' User entered 'No (N)'	(b) (4), (b) (6) System	16 Sep 2020 06:35:42
	System	16 Sep 2020 06:35:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-09-16T01:35:38', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6c5876ad-90c8-40ef-bbac-3a81a13701cb' User entered '16 Sep 2020 01:35'	System	16 Sep 2020 06:35:42
	System	16 Sep 2020 06:35:42

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '15 Sep 2020 12:00'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '16 Sep 2020 11:59'	(b) (4), (b) (6) System	09 Sep 2020 19:25:04

US3232157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	16 Sep 2020 19:39:05

US3232157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '16 Sep 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	16 Sep 2020 19:39:05

US3232157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	16 Sep 2020 19:39:05



US3232157

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	16 Sep 2020 19:39:05

US3232157

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	16 Sep 2020 19:39:09

US3232157

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'I'	(b) (4), (b) (6) System	16 Sep 2020 19:39:09

US3232157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Sep 2020 21:49:26

US3232157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '24 Sep 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Sep 2020 21:49:26

US3232157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Sep 2020 21:49:26

US3232157

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Sep 2020 21:49:26

US3232157

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Sep 2020 21:49:35



US3232157

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 21:49:35

US3232157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Sep 2020 16:41:09

US3232157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '30 Sep 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Sep 2020 16:41:09

US3232157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Sep 2020 16:41:09

US3232157

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Sep 2020 16:41:09

US3232157

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Sep 2020 16:41:14

US3232157

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'I'	(b) (4), (b) (6) System	30 Sep 2020 16:41:14

US3232157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-Query : Sample dated 04NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please update the details under page "Immunogenicity Assessment" under visit 3 for dated 04nov2020.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 05:34:41
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-Query : Sample dated 04NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please update the details under page "Immunogenicity Assessment" under visit 3 for dated 04nov2020.' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:04:31
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-Query : Sample dated 04NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please update the details under page "Immunogenicity Assessment" under visit 3 for dated 04nov2020.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 07:46:38
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04NOV2020 is reported under Visit 3 Day 57 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.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 07:44:10
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04NOV2020 is reported under Visit 3 Day 57 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.' answered with 'confirmed, sample was collected ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	17 Nov 2020 21:13:58



US3232157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04NOV2020 is reported under Visit 3 Day 57 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.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:06:41
User entered 'Yes (Y)'	Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:26

US3232157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '7 Oct 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:26

US3232157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Clinic (Clinic)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:26

US3232157

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'VISIT2'	(b) (4), (b) (6) System	07 Oct 2020 18:08:26

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Jerrica Sullivan (b) (4)	07 Oct 2020 21:20:42
	(b) (4)	

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '7 Oct 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '12:19'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42



US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '7 Oct 2020 12:19'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '98.5' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Oral (Oral)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '64'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'bpm'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '20'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'breaths/min'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42



US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '142'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '88'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Jerrica Sullivan (b) (4)	07 Oct 2020 21:20:42
	(b) (4)	

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '7 Oct 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '13:20'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42



US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '7 Oct 2020 13:20'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '97.5' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Other (Other)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'TEMPORAL'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '53'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'bpm'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '18'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'breaths/min'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42



US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '108'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '75'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	07 Oct 2020 21:20:42

US3232157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:33

US3232157

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '7 Oct 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:33

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:48

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:48



US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

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 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:48

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '7 Oct 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:48

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '13:03'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:48

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '7 Oct 2020 13:03'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:08:48

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'ONCE'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48



US3232157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:09:41

US3232157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '7 Oct 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:09:41

US3232157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '12:30'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:09:41

US3232157

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '7 Oct 2020 12:30'	(b) (4), (b) (6) System	07 Oct 2020 18:09:41

US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:11:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '7 Oct 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:09:52

US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Adreanna Pou (b) (4)	07 Oct 2020 18:09:52
	(b) (4)	

US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:09:52

US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '12:23'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:09:52



US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '7 Oct 2020 12:23'	(b) (4), (b) (6) System	07 Oct 2020 18:09:52

US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Adreanna Pou (b) (4)	07 Oct 2020 18:09:52
	(b) (4)	

US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:09:52

US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	07 Oct 2020 18:09:52

US3232157

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered empty.	(b) (4), (b) (6) System	07 Oct 2020 18:09:52

US3232157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	07 Oct 2020 18:19:35

US3232157

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '1'	(b) (4), (b) (6) System	07 Oct 2020 18:19:35

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:23:13', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '408df94b-877e-4a5b-8fe9-0de0de1633fc' User entered 'Yes (Y)'	(b) (4), (b) (6) System	07 Oct 2020 18:23:56
	System	07 Oct 2020 18:23:56

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:23:21', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '408df94b-877e-4a5b-8fe9-0de0de1633fc' User entered '97.5'	System	07 Oct 2020 18:23:56
	System	07 Oct 2020 18:23:56

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:23:44', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '408df94b-877e-4a5b-8fe9-0de0de1633fc' User entered 'No (N)'	System	07 Oct 2020 18:23:56
	System	07 Oct 2020 18:23:56

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:23:53', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '408df94b-877e-4a5b-8fe9-0de0de1633fc' User entered '07 Oct 2020 13:23'	System	07 Oct 2020 18:23:56
	System	07 Oct 2020 18:23:56

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '07 Oct 2020 13:23'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '07 Oct 2020 15:53'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
Data entry locked.	(b) (4), (b) (6)	
	System	07 Oct 2020 18:08:48
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:22:16', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9d4f5a4b-1a7b-4e15-a008-2fc37f41439a'	(b) (4), (b) (6) System	08 Oct 2020 00:22:36
User entered 'Yes (Y)'	System	08 Oct 2020 00:22:36



US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:22:22', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9d4f5a4b-1a7b-4e15-a008-2fc37f41439a' User entered '98.5'	(b) (4), (b) (6) System	08 Oct 2020 00:22:36
	System	08 Oct 2020 00:22:36

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:22:27', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9d4f5a4b-1a7b-4e15-a008-2fc37f41439a'	(b) (4), (b) (6)	
User entered 'No (N)'	System	08 Oct 2020 00:22:36
	System	08 Oct 2020 00:22:36

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:22:32', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9d4f5a4b-1a7b-4e15-a008-2fc37f41439a' User entered '07 Oct 2020 19:22'	(b) (4), (b) (6) System	08 Oct 2020 00:22:36
	System	08 Oct 2020 00:22:36

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '07 Oct 2020 16:48'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 2'	System	07 Oct 2020 18:08:48
	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:42:55', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '2bc93ecc-332f-4ab7-9673-4a969b98cbde' User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Oct 2020 22:44:51
	System	08 Oct 2020 22:44:51

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:44:42', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '2bc93ecc-332f-4ab7-9673-4a969b98cbde' User entered '97.8'	System	08 Oct 2020 22:44:51
	System	08 Oct 2020 22:44:51



US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:44:45', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '2bc93ecc-332f-4ab7-9673-4a969b98cbde' User entered 'No (N)'	System	08 Oct 2020 22:44:51
	System	08 Oct 2020 22:44:51

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:44:49', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '2bc93ecc-332f-4ab7-9673-4a969b98cbde' User entered '08 Oct 2020 17:44'	System	08 Oct 2020 22:44:51
	System	08 Oct 2020 22:44:51

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '08 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 3'	System	07 Oct 2020 18:08:48
	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:25:38', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7480f17e-9d7d-4e1a-8492-fec6fb5dcf13'	(b) (4), (b) (6) System	09 Oct 2020 22:25:55
User entered 'Yes (Y)'	System	09 Oct 2020 22:25:55

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:25:45', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7480f17e-9d7d-4e1a-8492-fec6fb5dcf13' User entered '98.0'	System	09 Oct 2020 22:25:55
	System	09 Oct 2020 22:25:55

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:25:48', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7480f17e-9d7d-4e1a-8492-fec6fb5dcf13'	(b) (4), (b) (6) System	09 Oct 2020 22:25:55
User entered 'No (N)'	System	09 Oct 2020 22:25:55



US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:25:50', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7480f17e-9d7d-4e1a-8492-fec6fb5dcf13' User entered '09 Oct 2020 17:25'	(b) (4), (b) (6) System	09 Oct 2020 22:25:55
	System	09 Oct 2020 22:25:55

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 4'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:09:58', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'aee7c2a7-c6ca-4dda-8113-a5158fb99833' User entered 'Yes (Y)'	(b) (4), (b) (6) System	11 Oct 2020 02:10:15
	System	11 Oct 2020 02:10:15

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:05', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'aee7c2a7-c6ca-4dda-8113-a5158fb99833' User entered '97.2'	System	11 Oct 2020 02:10:15
	System	11 Oct 2020 02:10:15

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:09', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'aee7c2a7-c6ca-4dda-8113-a5158fb99833' User entered 'No (N)'	(b) (4), (b) (6) System	11 Oct 2020 02:10:15
	System	11 Oct 2020 02:10:15

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:13', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'aee7c2a7-c6ca-4dda-8113-a5158fb99833' User entered '10 Oct 2020 21:10'	System	11 Oct 2020 02:10:15
	System	11 Oct 2020 02:10:15



US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 5'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:51:48', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d62985f-d900-4f59-bd08-305e2eda59c0'	(b) (4), (b) (6) System	11 Oct 2020 22:52:02
User entered 'Yes (Y)'	System	11 Oct 2020 22:52:02

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:51:54', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d62985f-d900-4f59-bd08-305e2eda59c0' User entered '98.0'	System	11 Oct 2020 22:52:02
	System	11 Oct 2020 22:52:02

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:51:58', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d62985f-d900-4f59-bd08-305e2eda59c0' User entered 'No (N)'	System	11 Oct 2020 22:52:02
	System	11 Oct 2020 22:52:02

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1d62985f-d900-4f59-bd08-305e2eda59c0' User entered '11 Oct 2020 17:52'	System	11 Oct 2020 22:52:02
	System	11 Oct 2020 22:52:02

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
Data entry locked.	(b) (4), (b) (6)	
User entered 'Day 6'	System	07 Oct 2020 18:08:48
	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:10', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '220340d2-9119-4839-9181-d2e630bae23a' User entered 'Yes (Y)'	System	12 Oct 2020 23:32:21
	System	12 Oct 2020 23:32:21

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:14', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '220340d2-9119-4839-9181-d2e630bae23a' User entered '97.3'	System	12 Oct 2020 23:32:21
	System	12 Oct 2020 23:32:21

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:17', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '220340d2-9119-4839-9181-d2e630bae23a' User entered 'No (N)'	System	12 Oct 2020 23:32:21
	System	12 Oct 2020 23:32:21

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:18', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '220340d2-9119-4839-9181-d2e630bae23a' User entered '12 Oct 2020 18:32'	System	12 Oct 2020 23:32:21
	System	12 Oct 2020 23:32:21

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 7'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:09:45', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9e1ac295-1802-49bf-a789-681eb7453daa' User entered 'Yes (Y)'	System	14 Oct 2020 12:10:04
	System	14 Oct 2020 12:10:04

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:09:49', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9e1ac295-1802-49bf-a789-681eb7453daa' User entered '97.7'	System	14 Oct 2020 12:10:04
	System	14 Oct 2020 12:10:04

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:09:55', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9e1ac295-1802-49bf-a789-681eb7453daa' User entered 'No (N)'	System	14 Oct 2020 12:10:04
	System	14 Oct 2020 12:10:04

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:09:58', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9e1ac295-1802-49bf-a789-681eb7453daa' User entered '14 Oct 2020 07:09'	System	14 Oct 2020 12:10:04
	System	14 Oct 2020 12:10:04

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:24:21', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '96bbe9f4-40a4-41ea-9c6e-caebb7c18136'	(b) (4), (b) (6) System	07 Oct 2020 18:25:44
User entered 'None (1)'	System	07 Oct 2020 18:25:44

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:25:17', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '96bbe9f4-40a4-41ea-9c6e-caebb7c18136'	(b) (4), (b) (6) System	07 Oct 2020 18:25:44
User entered 'No (N)'	System	07 Oct 2020 18:25:44

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:25:21', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '96bbe9f4-40a4-41ea-9c6e-caebb7c18136'	(b) (4), (b) (6) System	07 Oct 2020 18:25:44
User entered 'No (N)'	System	07 Oct 2020 18:25:44

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:25:36', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '96bbe9f4-40a4-41ea-9c6e-caebb7c18136'	(b) (4), (b) (6) System	07 Oct 2020 18:25:44
User entered 'None (1)'	System	07 Oct 2020 18:25:44

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:25:41', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '96bbe9f4-40a4-41ea-9c6e-caebb7c18136' User entered '07 Oct 2020 13:25'	System	07 Oct 2020 18:25:44
	System	07 Oct 2020 18:25:44

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '07 Oct 2020 13:23'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '07 Oct 2020 15:53'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:22:52', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '52398fb8-efd2-4cb7-84f2-487d66ea3398'	(b) (4), (b) (6) System	08 Oct 2020 00:25:07
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 00:25:07

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:24:42', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '52398fb8-efd2-4cb7-84f2-487d66ea3398'	(b) (4), (b) (6) System	08 Oct 2020 00:25:07
User entered 'No (N)'	System	08 Oct 2020 00:25:07

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:24:46', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '52398fb8-efd2-4cb7-84f2-487d66ea3398'	(b) (4), (b) (6) System	08 Oct 2020 00:25:07
User entered 'No (N)'	System	08 Oct 2020 00:25:07

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:24:58', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '52398fb8-efd2-4cb7-84f2-487d66ea3398'	(b) (4), (b) (6) System	08 Oct 2020 00:25:07
User entered 'None (1)'	System	08 Oct 2020 00:25:07

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:25:04', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '52398fb8-efd2-4cb7-84f2-487d66ea3398'	(b) (4), (b) (6) System	08 Oct 2020 00:25:07
User entered '07 Oct 2020 19:25'	System	08 Oct 2020 00:25:07

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '07 Oct 2020 16:48'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 2'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:03', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7cf28427-be54-4354-b5a1-1bf68d8590a5'	(b) (4), (b) (6) System	08 Oct 2020 22:45:18
User entered 'None (1)'	System	08 Oct 2020 22:45:18

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:06', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7cf28427-be54-4354-b5a1-1bf68d8590a5'	(b) (4), (b) (6) System	08 Oct 2020 22:45:18
User entered 'No (N)'	System	08 Oct 2020 22:45:18

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:08', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7cf28427-be54-4354-b5a1-1bf68d8590a5'	(b) (4), (b) (6) System	08 Oct 2020 22:45:18
User entered 'No (N)'	System	08 Oct 2020 22:45:18

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:15', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7cf28427-be54-4354-b5a1-1bf68d8590a5'	(b) (4), (b) (6) System	08 Oct 2020 22:45:18
User entered 'None (1)'	System	08 Oct 2020 22:45:18

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:17', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7cf28427-be54-4354-b5a1-1bf68d8590a5'	(b) (4), (b) (6) System	08 Oct 2020 22:45:18
User entered '08 Oct 2020 17:45'	System	08 Oct 2020 22:45:18

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '08 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 3'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:06', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'f34ef73c-6f34-4a1a-b463-e019fa84aca6'	(b) (4), (b) (6) System	09 Oct 2020 22:26:24
User entered 'None (1)'	System	09 Oct 2020 22:26:24

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:08', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'f34ef73c-6f34-4a1a-b463-e019fa84aca6'	(b) (4), (b) (6) System	09 Oct 2020 22:26:24
User entered 'No (N)'	System	09 Oct 2020 22:26:24

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:10', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'f34ef73c-6f34-4a1a-b463-e019fa84aca6'	(b) (4), (b) (6) System	09 Oct 2020 22:26:24
User entered 'No (N)'	System	09 Oct 2020 22:26:24

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:17', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'f34ef73c-6f34-4a1a-b463-e019fa84aca6'	(b) (4), (b) (6) System	09 Oct 2020 22:26:24
User entered 'None (1)'	System	09 Oct 2020 22:26:24

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:22', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'f34ef73c-6f34-4a1a-b463-e019fa84aca6'	(b) (4), (b) (6) System	09 Oct 2020 22:26:24
User entered '09 Oct 2020 17:26'	System	09 Oct 2020 22:26:24

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 4'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:25', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a2d93881-46c3-442b-bf99-fbea9aad8a6c'	(b) (4), (b) (6) System	11 Oct 2020 02:10:47
User entered 'None (1)'	System	11 Oct 2020 02:10:47

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:28', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a2d93881-46c3-442b-bf99-fbea9aad8a6c'	(b) (4), (b) (6) System	11 Oct 2020 02:10:47
User entered 'No (N)'	System	11 Oct 2020 02:10:47

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:30', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a2d93881-46c3-442b-bf99-fbea9aad8a6c'	(b) (4), (b) (6) System	11 Oct 2020 02:10:47
User entered 'No (N)'	System	11 Oct 2020 02:10:47

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:43', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a2d93881-46c3-442b-bf99-fbea9aad8a6c'	(b) (4), (b) (6) System	11 Oct 2020 02:10:47
User entered 'None (1)'	System	11 Oct 2020 02:10:47

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:45', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a2d93881-46c3-442b-bf99-fbea9aad8a6c' User entered '10 Oct 2020 21:10'	System	11 Oct 2020 02:10:47
	System	11 Oct 2020 02:10:47

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 5'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:10', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a6caa467-20e2-4677-9f4c-064a267621d4'	(b) (4), (b) (6) System	11 Oct 2020 22:52:21
User entered 'None (1)'	System	11 Oct 2020 22:52:21

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:13', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a6caa467-20e2-4677-9f4c-064a267621d4'	(b) (4), (b) (6) System	11 Oct 2020 22:52:21
User entered 'No (N)'	System	11 Oct 2020 22:52:21

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:16', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a6caa467-20e2-4677-9f4c-064a267621d4' User entered 'No (N)'	System	11 Oct 2020 22:52:21
	System	11 Oct 2020 22:52:21

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:18', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a6caa467-20e2-4677-9f4c-064a267621d4'	(b) (4), (b) (6) System	11 Oct 2020 22:52:21
User entered 'None (1)'	System	11 Oct 2020 22:52:21

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:20', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a6caa467-20e2-4677-9f4c-064a267621d4' User entered '11 Oct 2020 17:52'	System	11 Oct 2020 22:52:21
	System	11 Oct 2020 22:52:21

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 6'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:24', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6130d34b-de17-407e-b2f4-f11c51617bf7' User entered 'None (1)'	System	12 Oct 2020 23:32:36
	System	12 Oct 2020 23:32:36

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:27', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6130d34b-de17-407e-b2f4-f11c51617bf7'	(b) (4), (b) (6) System	12 Oct 2020 23:32:36
User entered 'No (N)'	System	12 Oct 2020 23:32:36

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:30', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6130d34b-de17-407e-b2f4-f11c51617bf7'	(b) (4), (b) (6) System	12 Oct 2020 23:32:36
User entered 'No (N)'	System	12 Oct 2020 23:32:36

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:32', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6130d34b-de17-407e-b2f4-f11c51617bf7'	(b) (4), (b) (6) System	12 Oct 2020 23:32:36
User entered 'None (1)'	System	12 Oct 2020 23:32:36

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '6130d34b-de17-407e-b2f4-f11c51617bf7' User entered '12 Oct 2020 18:32'	System	12 Oct 2020 23:32:36
	System	12 Oct 2020 23:32:36

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 7'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:03', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9de41da9-8b1b-46c7-8654-44a255140868'	(b) (4), (b) (6) System	14 Oct 2020 12:10:20
User entered 'None (1)'	System	14 Oct 2020 12:10:20

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:09', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9de41da9-8b1b-46c7-8654-44a255140868'	(b) (4), (b) (6) System	14 Oct 2020 12:10:20
User entered 'No (N)'	System	14 Oct 2020 12:10:20

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:13', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9de41da9-8b1b-46c7-8654-44a255140868'	(b) (4), (b) (6) System	14 Oct 2020 12:10:20
User entered 'No (N)'	System	14 Oct 2020 12:10:20

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:16', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9de41da9-8b1b-46c7-8654-44a255140868'	(b) (4), (b) (6) System	14 Oct 2020 12:10:20
User entered 'None (1)'	System	14 Oct 2020 12:10:20

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:18', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '9de41da9-8b1b-46c7-8654-44a255140868' User entered '14 Oct 2020 07:10'	System	14 Oct 2020 12:10:20
	System	14 Oct 2020 12:10:20

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:25:49', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c5156676-af1c-4d60-9439-4c0effe3cccd' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 18:26:14
	System	07 Oct 2020 18:26:14

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:25:51', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c5156676-af1c-4d60-9439-4c0effe3cccd' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 18:26:14
	System	07 Oct 2020 18:26:14

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:25:55', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c5156676-af1c-4d60-9439-4c0effe3cccd' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 18:26:14
	System	07 Oct 2020 18:26:14

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:26:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c5156676-af1c-4d60-9439-4c0effe3cccd' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 18:26:14
	System	07 Oct 2020 18:26:14

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:26:02', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c5156676-af1c-4d60-9439-4c0effe3cccd' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 18:26:14
	System	07 Oct 2020 18:26:14

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:26:05', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c5156676-af1c-4d60-9439-4c0effe3cccd' User entered 'None (0)'	(b) (4), (b) (6) System	07 Oct 2020 18:26:14
	System	07 Oct 2020 18:26:14

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:26:09', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c5156676-af1c-4d60-9439-4c0effe3cccd' User entered 'No (N)'	System	07 Oct 2020 18:26:14
	System	07 Oct 2020 18:26:14

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T13:26:12', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c5156676-af1c-4d60-9439-4c0effe3cccd' User entered '07 Oct 2020 13:26'	System	07 Oct 2020 18:26:14
	System	07 Oct 2020 18:26:14



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '07 Oct 2020 13:23'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '07 Oct 2020 15:53'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
Data entry locked.	(b) (4), (b) (6)	
	System	07 Oct 2020 18:08:48
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:25:08', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '00bdf758-3a65-44f8-b27e-6890c3516067' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 00:25:33
	System	08 Oct 2020 00:25:33

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:25:10', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '00bdf758-3a65-44f8-b27e-6890c3516067' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 00:25:33
	System	08 Oct 2020 00:25:33

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:25:12', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '00bdf758-3a65-44f8-b27e-6890c3516067' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 00:25:33
	System	08 Oct 2020 00:25:33

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:25:15', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '00bdf758-3a65-44f8-b27e-6890c3516067' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 00:25:33
	System	08 Oct 2020 00:25:33

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:25:17', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '00bdf758-3a65-44f8-b27e-6890c3516067' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 00:25:33
	System	08 Oct 2020 00:25:33



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:25:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '00bdf758-3a65-44f8-b27e-6890c3516067' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 00:25:33
	System	08 Oct 2020 00:25:33

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:25:23', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '00bdf758-3a65-44f8-b27e-6890c3516067' User entered 'No (N)'	(b) (4), (b) (6) System	08 Oct 2020 00:25:33
	System	08 Oct 2020 00:25:33

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-07T19:25:27', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '00bdf758-3a65-44f8-b27e-6890c3516067' User entered '07 Oct 2020 19:25'	(b) (4), (b) (6) System	08 Oct 2020 00:25:33
	System	08 Oct 2020 00:25:33

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '07 Oct 2020 16:48'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 2'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:20', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a80dd127-3504-41d2-893b-96501936622c' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 22:45:37
	System	08 Oct 2020 22:45:37

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:22', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a80dd127-3504-41d2-893b-96501936622c' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 22:45:37
	System	08 Oct 2020 22:45:37



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:23', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a80dd127-3504-41d2-893b-96501936622c' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 22:45:37
	System	08 Oct 2020 22:45:37

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:26', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a80dd127-3504-41d2-893b-96501936622c' User entered 'None (0)'	System	08 Oct 2020 22:45:37
	System	08 Oct 2020 22:45:37

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:28', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a80dd127-3504-41d2-893b-96501936622c' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 22:45:37
	System	08 Oct 2020 22:45:37

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:30', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a80dd127-3504-41d2-893b-96501936622c' User entered 'None (0)'	(b) (4), (b) (6) System	08 Oct 2020 22:45:37
	System	08 Oct 2020 22:45:37

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a80dd127-3504-41d2-893b-96501936622c'	(b) (4), (b) (6) System	08 Oct 2020 22:45:37
User entered 'No (N)'	System	08 Oct 2020 22:45:37

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-08T17:45:36', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a80dd127-3504-41d2-893b-96501936622c' User entered '08 Oct 2020 17:45'	(b) (4), (b) (6) System	08 Oct 2020 22:45:37
	System	08 Oct 2020 22:45:37

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '08 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 3'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:26', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3cc2d654-05b4-4c18-869c-bc918aade087' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 22:26:49
	System	09 Oct 2020 22:26:49

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:28', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3cc2d654-05b4-4c18-869c-bc918aade087' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 22:26:49
	System	09 Oct 2020 22:26:49

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:30', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3cc2d654-05b4-4c18-869c-bc918aade087' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 22:26:49
	System	09 Oct 2020 22:26:49

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:32', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3cc2d654-05b4-4c18-869c-bc918aade087' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 22:26:49
	System	09 Oct 2020 22:26:49

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3cc2d654-05b4-4c18-869c-bc918aade087' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 22:26:49
	System	09 Oct 2020 22:26:49

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:35', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3cc2d654-05b4-4c18-869c-bc918aade087' User entered 'None (0)'	(b) (4), (b) (6) System	09 Oct 2020 22:26:49
	System	09 Oct 2020 22:26:49

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:42', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3cc2d654-05b4-4c18-869c-bc918aade087'	(b) (4), (b) (6) System	09 Oct 2020 22:26:49
User entered 'No (N)'	System	09 Oct 2020 22:26:49



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-09T17:26:45', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3cc2d654-05b4-4c18-869c-bc918aade087' User entered '09 Oct 2020 17:26'	(b) (4), (b) (6) System	09 Oct 2020 22:26:49
	System	09 Oct 2020 22:26:49

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '09 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 4'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:50', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1b040a3b-38b9-4736-82dc-77a1e97afc91' User entered 'None (0)'	System	11 Oct 2020 02:11:10
	System	11 Oct 2020 02:11:10

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:53', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1b040a3b-38b9-4736-82dc-77a1e97afc91' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 02:11:10
	System	11 Oct 2020 02:11:10

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:55', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1b040a3b-38b9-4736-82dc-77a1e97afc91' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 02:11:10
	System	11 Oct 2020 02:11:10

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:57', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1b040a3b-38b9-4736-82dc-77a1e97afc91' User entered 'None (0)'	System	11 Oct 2020 02:11:10
	System	11 Oct 2020 02:11:10



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:10:59', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1b040a3b-38b9-4736-82dc-77a1e97afc91' User entered 'None (0)'	(b) (4), (b) (6) System	11 Oct 2020 02:11:10
	System	11 Oct 2020 02:11:10

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:11:02', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1b040a3b-38b9-4736-82dc-77a1e97afc91' User entered 'None (0)'	System	11 Oct 2020 02:11:10
	System	11 Oct 2020 02:11:10

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:11:06', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1b040a3b-38b9-4736-82dc-77a1e97afc91'	(b) (4), (b) (6) System	11 Oct 2020 02:11:10
User entered 'No (N)'	System	11 Oct 2020 02:11:10

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-10T21:11:08', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1b040a3b-38b9-4736-82dc-77a1e97afc91' User entered '10 Oct 2020 21:11'	(b) (4), (b) (6) System	11 Oct 2020 02:11:10
	System	11 Oct 2020 02:11:10

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '10 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 5'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:24', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b3eb5e9d-bc84-4052-9f4e-9702d1bfba15' User entered 'None (0)'	System	11 Oct 2020 22:52:44
	System	11 Oct 2020 22:52:44



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:26', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b3eb5e9d-bc84-4052-9f4e-9702d1bfba15' User entered 'None (0)'	System	11 Oct 2020 22:52:44
	System	11 Oct 2020 22:52:44

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:28', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b3eb5e9d-bc84-4052-9f4e-9702d1bfba15' User entered 'None (0)'	System	11 Oct 2020 22:52:44
	System	11 Oct 2020 22:52:44

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:32', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b3eb5e9d-bc84-4052-9f4e-9702d1bfba15' User entered 'None (0)'	System	11 Oct 2020 22:52:44
	System	11 Oct 2020 22:52:44

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:33', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b3eb5e9d-bc84-4052-9f4e-9702d1bfba15' User entered 'None (0)'	System	11 Oct 2020 22:52:44
	System	11 Oct 2020 22:52:44

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:35', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b3eb5e9d-bc84-4052-9f4e-9702d1bfba15' User entered 'None (0)'	System	11 Oct 2020 22:52:44
	System	11 Oct 2020 22:52:44

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

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) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:37', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b3eb5e9d-bc84-4052-9f4e-9702d1bfba15' User entered 'No (N)'	System	11 Oct 2020 22:52:44
	System	11 Oct 2020 22:52:44

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-11T17:52:39', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b3eb5e9d-bc84-4052-9f4e-9702d1bfba15'	(b) (4), (b) (6) System	11 Oct 2020 22:52:44
User entered '11 Oct 2020 17:52'	System	11 Oct 2020 22:52:44

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '11 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 6'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:50', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7c363ddc-9bc0-4f01-95c0-58eebaffd543'	(b) (4), (b) (6) System	12 Oct 2020 23:33:08
User entered 'None (0)'	System	12 Oct 2020 23:33:08

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:52', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7c363ddc-9bc0-4f01-95c0-58eebaffd543' User entered 'None (0)'	System	12 Oct 2020 23:33:08
	System	12 Oct 2020 23:33:08

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:55', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7c363ddc-9bc0-4f01-95c0-58eebaffd543' User entered 'None (0)'	System	12 Oct 2020 23:33:08
	System	12 Oct 2020 23:33:08

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:57', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7c363ddc-9bc0-4f01-95c0-58eebaffd543' User entered 'None (0)'	System	12 Oct 2020 23:33:08
	System	12 Oct 2020 23:33:08

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:32:58', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7c363ddc-9bc0-4f01-95c0-58eebaffd543' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 23:33:08
	System	12 Oct 2020 23:33:08

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:33:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7c363ddc-9bc0-4f01-95c0-58eebaffd543' User entered 'None (0)'	(b) (4), (b) (6) System	12 Oct 2020 23:33:08
	System	12 Oct 2020 23:33:08



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:33:02', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7c363ddc-9bc0-4f01-95c0-58eebaffd543'	(b) (4), (b) (6) System	12 Oct 2020 23:33:08
User entered 'No (N)'	System	12 Oct 2020 23:33:08

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-12T18:33:04', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7c363ddc-9bc0-4f01-95c0-58eebaffd543' User entered '12 Oct 2020 18:33'	System	12 Oct 2020 23:33:08
	System	12 Oct 2020 23:33:08

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '12 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	07 Oct 2020 18:08:48
User entered 'Day 7'	System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:24', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c6579784-3f21-4c14-a233-c48df007d861' User entered 'None (0)'	System	14 Oct 2020 12:10:50
	System	14 Oct 2020 12:10:50

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:26', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c6579784-3f21-4c14-a233-c48df007d861' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 12:10:50
	System	14 Oct 2020 12:10:50

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:28', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c6579784-3f21-4c14-a233-c48df007d861' User entered 'None (0)'	System	14 Oct 2020 12:10:50
	System	14 Oct 2020 12:10:50



US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:31', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c6579784-3f21-4c14-a233-c48df007d861' User entered 'None (0)'	System	14 Oct 2020 12:10:50
	System	14 Oct 2020 12:10:50

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:33', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c6579784-3f21-4c14-a233-c48df007d861' User entered 'None (0)'	(b) (4), (b) (6) System	14 Oct 2020 12:10:50
	System	14 Oct 2020 12:10:50

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c6579784-3f21-4c14-a233-c48df007d861' User entered 'None (0)'	System	14 Oct 2020 12:10:50
	System	14 Oct 2020 12:10:50

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:39', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c6579784-3f21-4c14-a233-c48df007d861' User entered 'No (N)'	(b) (4), (b) (6) System	14 Oct 2020 12:10:50
	System	14 Oct 2020 12:10:50

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-10-14T07:10:45', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c6579784-3f21-4c14-a233-c48df007d861' User entered '14 Oct 2020 07:10'	(b) (4), (b) (6) System	14 Oct 2020 12:10:50
	System	14 Oct 2020 12:10:50

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '13 Oct 2020 12:00'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:11:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	07 Oct 2020 18:08:48

US3232157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 19:09:40



US3232157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '14 Oct 2020'	(b) (4) Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 19:09:40

US3232157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 19:09:40

US3232157

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 19:09:40

US3232157

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	14 Oct 2020 19:09:44

US3232157

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'I'	(b) (4), (b) (6) System	14 Oct 2020 19:09:44

US3232157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	23 Oct 2020 16:52:25

US3232157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '21 Oct 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	23 Oct 2020 16:52:25

US3232157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	23 Oct 2020 16:52:25



US3232157

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	23 Oct 2020 16:52:25

US3232157

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	23 Oct 2020 16:52:18

US3232157

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'I'	(b) (4), (b) (6) System	23 Oct 2020 16:52:18

US3232157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Oct 2020 16:37:46

US3232157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '28 Oct 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Oct 2020 16:37:46

US3232157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Oct 2020 16:37:46

US3232157

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	28 Oct 2020 16:37:46
	(b) (4)	

US3232157

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Oct 2020 16:37:50



US3232157

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '1'	(b) (4), (b) (6) System	28 Oct 2020 16:37:50

US3232157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:04:39

US3232157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '04 Nov 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:04:39

US3232157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Clinic (Clinic)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:04:39

US3232157

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'VISIT3'	(b) (4), (b) (6) System	24 Nov 2020 18:04:39

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User closed query 'Per CDM: Please review 'Date of assessment' and update as per the required format (dd MMM yyyy). Else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 12:32:32
Query 'Per CDM: Please review 'Date of assessment' and update as per the required format (dd MMM yyyy). Else clarify' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	02 Dec 2020 13:44:45
User entered '04 Nov 2020' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	02 Dec 2020 13:44:37
User opened query 'Per CDM: Please review 'Date of assessment' and update as per the required format (dd MMM yyyy). Else clarify' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 09:29:24
User entered '4 Nov 2020'	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '12:35'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22



US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	
User entered '04 Nov 2020 12:35'	System	02 Dec 2020 13:44:37
User entered '4 Nov 2020 12:35'	System	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '98.1' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Oral (Oral)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '54'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'bpm'	(b) (4), (b) (6) System	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '20'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Nov 2020 18:05:22



US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '120'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '69'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'mmHg'	(b) (4), (b) (6) System	24 Nov 2020 18:05:22

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	

US3232157

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
	(b) (4), (b) (6)	

US3232157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	24 Nov 2020 21:13:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 21:13:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 21:13:11
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:05:03
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:03

US3232157

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '4 Nov 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:05:03



US3232157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:04:53

US3232157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '4 Nov 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:04:53

US3232157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered '12:34'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:04:53

US3232157

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '4 Nov 2020 12:34'	(b) (4), (b) (6) System	24 Nov 2020 18:04:53

US3232157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	18 Feb 2021 16:11:24
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	24 Nov 2020 18:04:57

US3232157

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered '1'	(b) (4), (b) (6) System	24 Nov 2020 18:04:57

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
Amendment Manager: DataPoint Inactivated.	System	01 Apr 2021 17:41:56
Data entry locked.	System	20 Nov 2020 06:44:51
User entered 'Day 64'	System	09 Sep 2020 19:25:04

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51



US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51



US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51



US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:44:51



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
Amendment Manager: DataPoint Inactivated.	System	01 Apr 2021 17:41:56
Data entry locked.	System	20 Nov 2020 06:44:51
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 19:25:04
	System	09 Sep 2020 19:25:04

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
Amendment Manager: DataPoint Inactivated.	System	01 Apr 2021 17:41:56
Data entry locked.	System	20 Nov 2020 06:44:51
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 19:25:04
	System	09 Sep 2020 19:25:04

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered 'Day 71'	System	09 Sep 2020 19:25:04

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-11-16T06:32:39', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'e1032961-21a1-4e2c-af38-a941dcdcfb87'	(b) (4), (b) (6) System	16 Nov 2020 12:36:50
User entered 'No (N)'	System	16 Nov 2020 12:36:50

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-11-16T06:36:39', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'e1032961-21a1-4e2c-af38-a941dcdcfb87'	(b) (4), (b) (6) System	16 Nov 2020 12:36:50
User entered 'No (N)'	System	16 Nov 2020 12:36:50

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-11-16T06:36:46', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'e1032961-21a1-4e2c-af38-a941dcdcfb87'	(b) (4), (b) (6) System	16 Nov 2020 12:36:50
User entered '16 Nov 2020 06:36:46'	System	16 Nov 2020 12:36:50

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 19:25:04

US3232157

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:42:59
	(b) (4), (b) (6)	
Data entry locked.	System	09 Sep 2020 19:25:04
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 19:25:04



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-01T10:27:38', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '48203f52-9bbf-49b7-a8a4-a72200a8adbd' User entered 'No (N)'	System	01 Dec 2020 16:27:53
	System	01 Dec 2020 16:27:53

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-01T10:27:46', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '48203f52-9bbf-49b7-a8a4-a72200a8adbd' User entered 'No (N)'	System	01 Dec 2020 16:27:53
	System	01 Dec 2020 16:27:53

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-01T10:27:52', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '48203f52-9bbf-49b7-a8a4-a72200a8adbd' User entered '01 Dec 2020 10:27:52'	System	01 Dec 2020 16:27:53
	System	01 Dec 2020 16:27:53

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-04T07:37:57', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3d90ecdb-de40-4eb3-b801-f2359903c16a'	System	04 Dec 2020 13:38:16
User entered 'No (N)'	System	04 Dec 2020 13:38:16

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-04T07:38:06', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3d90ecdb-de40-4eb3-b801-f2359903c16a'	System	04 Dec 2020 13:38:16
User entered 'No (N)'	System	04 Dec 2020 13:38:16

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-04T07:38:11', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3d90ecdb-de40-4eb3-b801-f2359903c16a' User entered '04 Dec 2020 07:38:11'	System	04 Dec 2020 13:38:16
	System	04 Dec 2020 13:38:16

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-13T12:15:49', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3dc93f7b-2ac0-4c92-8c24-d699204612c4'	System	13 Dec 2020 18:16:12
User entered 'No (N)'	System	13 Dec 2020 18:16:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-13T12:16:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3dc93f7b-2ac0-4c92-8c24-d699204612c4'	System	13 Dec 2020 18:16:12
User entered 'No (N)'	System	13 Dec 2020 18:16:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-13T12:16:08', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3dc93f7b-2ac0-4c92-8c24-d699204612c4' User entered '13 Dec 2020 12:16:08'	System	13 Dec 2020 18:16:12
	System	13 Dec 2020 18:16:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-18T06:16:18', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '08a98928-366b-42e4-bca0-0cae12878f1f'	System	18 Dec 2020 12:16:53
User entered 'No (N)'	System	18 Dec 2020 12:16:53

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-18T06:16:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '08a98928-366b-42e4-bca0-0cae12878f1f'	System	18 Dec 2020 12:16:53
User entered 'No (N)'	System	18 Dec 2020 12:16:53



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67A1805D-A672-44B9-A46F-68002CB4AFA0)', Time: '2020-12-18T06:16:48', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '08a98928-366b-42e4-bca0-0cae12878f1f' User entered '18 Dec 2020 06:16:48'	System	18 Dec 2020 12:16:53
	System	18 Dec 2020 12:16:53

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:35:20', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered 'Yes (Y)'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:35:26', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered 'Yes (Y)'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:35:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b'	System	10 Jan 2021 16:31:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:35:41', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b'	System	10 Jan 2021 16:31:12
User entered 'Yes (Y)'	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '1'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '1'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '1'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b'	System	10 Jan 2021 16:31:12
User entered '1'	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '1'	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '1'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '0'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b'	System	10 Jan 2021 16:31:12
User entered '0'	System	10 Jan 2021 16:31:12

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:22', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b'	System	10 Jan 2021 16:31:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 16:31:12



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:32', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered 'No (N)'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-08T09:36:43', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'c27eef94-7929-45c5-a175-23154432598b' User entered '08 Jan 2021 09:36:43'	System	10 Jan 2021 16:31:12
	System	10 Jan 2021 16:31:12

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-15T07:58:44', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'aa76dde4-ed71-4573-9ad7-9eaf93e37042'	System	15 Jan 2021 13:59:40
User entered 'Yes (Y)'	System	15 Jan 2021 13:59:40

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-15T07:59:01', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'aa76dde4-ed71-4573-9ad7-9eaf93e37042'	System	15 Jan 2021 13:59:40
User entered 'No (N)'	System	15 Jan 2021 13:59:40

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-15T07:59:18', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'aa76dde4-ed71-4573-9ad7-9eaf93e37042'	System	15 Jan 2021 13:59:40
User entered 'No (N)'	System	15 Jan 2021 13:59:40



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-15T07:59:31', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'aa76dde4-ed71-4573-9ad7-9eaf93e37042'	System	15 Jan 2021 13:59:40
User entered 'No (N)'	System	15 Jan 2021 13:59:40

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-15T07:59:36', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'aa76dde4-ed71-4573-9ad7-9eaf93e37042'	System	15 Jan 2021 13:59:40
User entered '15 Jan 2021 07:59:36'	System	15 Jan 2021 13:59:40

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-22T08:04:24', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'd69bd6ac-4ad1-4bf4-aa86-d11684a47168'	System	22 Jan 2021 14:04:36
User entered 'No (N)'	System	22 Jan 2021 14:04:36

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-22T08:03:47', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'd69bd6ac-4ad1-4bf4-aa86-d11684a47168'	System	22 Jan 2021 14:04:36
User entered 'No (N)'	System	22 Jan 2021 14:04:36

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-01-22T08:04:34', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'd69bd6ac-4ad1-4bf4-aa86-d11684a47168' User entered '22 Jan 2021 08:04:34'	System	22 Jan 2021 14:04:36
	System	22 Jan 2021 14:04:36



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-01T09:03:19', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'e5a195e4-209f-49e3-b22b-481a6af341f8'	System	01 Feb 2021 15:03:34
User entered 'No (N)'	System	01 Feb 2021 15:03:34

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-01T09:03:26', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'e5a195e4-209f-49e3-b22b-481a6af341f8'	System	01 Feb 2021 15:03:34
User entered 'No (N)'	System	01 Feb 2021 15:03:34

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-01T09:03:29', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'e5a195e4-209f-49e3-b22b-481a6af341f8'	System	01 Feb 2021 15:03:34
User entered '01 Feb 2021 09:03:29'	System	01 Feb 2021 15:03:34

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-05T06:28:56', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3366660d-fc87-44c6-9902-9e3827a79efa' User entered 'No (N)'	System	05 Feb 2021 12:29:15
	System	05 Feb 2021 12:29:15

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-05T06:29:09', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3366660d-fc87-44c6-9902-9e3827a79efa' User entered 'No (N)'	System	05 Feb 2021 12:29:15
	System	05 Feb 2021 12:29:15

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-05T06:29:12', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '3366660d-fc87-44c6-9902-9e3827a79efa' User entered '05 Feb 2021 06:29:12'	System	05 Feb 2021 12:29:15
	System	05 Feb 2021 12:29:15

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-12T07:57:03', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '215f3fa2-40c9-4927-8883-65ef35d938c7'	System	12 Feb 2021 13:57:57
User entered 'Yes (Y)'	System	12 Feb 2021 13:57:57



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-12T07:57:14', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '215f3fa2-40c9-4927-8883-65ef35d938c7'	System	12 Feb 2021 13:57:57
User entered 'No (N)'	System	12 Feb 2021 13:57:57

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-12T07:57:23', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '215f3fa2-40c9-4927-8883-65ef35d938c7'	System	12 Feb 2021 13:57:57
User entered 'No (N)'	System	12 Feb 2021 13:57:57

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-12T07:57:29', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '215f3fa2-40c9-4927-8883-65ef35d938c7'	System	12 Feb 2021 13:57:57
User entered 'No (N)'	System	12 Feb 2021 13:57:57

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-12T07:57:53', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '215f3fa2-40c9-4927-8883-65ef35d938c7' User entered '12 Feb 2021 07:57:53'	System	12 Feb 2021 13:57:57
	System	12 Feb 2021 13:57:57

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-19T06:41:54', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a2c3fb94-79e7-4b63-b88b-1709e62bcb60'	System	19 Feb 2021 12:42:13
User entered 'No (N)'	System	19 Feb 2021 12:42:13



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-19T06:41:49', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a2c3fb94-79e7-4b63-b88b-1709e62bcb60'	System	19 Feb 2021 12:42:13
User entered 'No (N)'	System	19 Feb 2021 12:42:13

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-19T06:42:11', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'a2c3fb94-79e7-4b63-b88b-1709e62bcb60' User entered '19 Feb 2021 06:42:11'	System	19 Feb 2021 12:42:13
	System	19 Feb 2021 12:42:13

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-28T12:00:45-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '0a5c6255-ad96-4693-9d5e-5418187ecbd2'	System	28 Feb 2021 18:02:18
User entered 'Yes (Y)'	System	28 Feb 2021 18:02:18

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-28T12:00:51-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '0a5c6255-ad96-4693-9d5e-5418187ecbd2'	System	28 Feb 2021 18:02:18
User entered 'No (N)'	System	28 Feb 2021 18:02:18

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-28T12:00:55-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '0a5c6255-ad96-4693-9d5e-5418187ecbd2'	System	28 Feb 2021 18:02:18
User entered 'No (N)'	System	28 Feb 2021 18:02:18



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-28T12:01:03-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '0a5c6255-ad96-4693-9d5e-5418187ecbd2'	System	28 Feb 2021 18:02:18
User entered 'Yes (Y)'	System	28 Feb 2021 18:02:18

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-28T12:01:09-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '0a5c6255-ad96-4693-9d5e-5418187ecbd2'	System	28 Feb 2021 18:02:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Feb 2021 18:02:18

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-28T12:01:13-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '0a5c6255-ad96-4693-9d5e-5418187ecbd2'	System	28 Feb 2021 18:02:18
User entered '28 Feb 2021 18:01:13'	System	28 Feb 2021 18:02:18

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-03-07T13:54:16-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '5c6890fa-9a12-4439-8ee7-edeb3ca4b2b1'	System	07 Mar 2021 19:54:30
User entered 'No (N)'	System	07 Mar 2021 19:54:30

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-03-07T13:54:19-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '5c6890fa-9a12-4439-8ee7-edeb3ca4b2b1'	System	07 Mar 2021 19:54:30
User entered 'No (N)'	System	07 Mar 2021 19:54:30



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-03-07T13:54:23-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '5c6890fa-9a12-4439-8ee7-edeb3ca4b2b1' User entered '07 Mar 2021 13:54:23'	System	07 Mar 2021 19:54:30
	System	07 Mar 2021 19:54:30

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-03-19T08:06:20-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bee15bd3-7019-45c6-8032-3d9c4aeff4d4'	System	19 Mar 2021 13:06:30
User entered 'No (N)'	System	19 Mar 2021 13:06:30



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-03-19T08:06:24-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bee15bd3-7019-45c6-8032-3d9c4aef4d4'	System	19 Mar 2021 13:06:30
User entered 'No (N)'	System	19 Mar 2021 13:06:30

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-03-19T08:06:26-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'bee15bd3-7019-45c6-8032-3d9c4aef4d4'	System	19 Mar 2021 13:06:30
User entered '19 Mar 2021 08:06:26'	System	19 Mar 2021 13:06:30

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-03-29T08:25:39-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '420d2543-c421-4d30-9b25-569995cb4057'	System	29 Mar 2021 13:25:47
User entered 'No (N)'	System	29 Mar 2021 13:25:47

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-03-29T08:25:42-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '420d2543-c421-4d30-9b25-569995cb4057'	System	29 Mar 2021 13:25:47
User entered 'No (N)'	System	29 Mar 2021 13:25:47

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-03-29T08:25:44-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '420d2543-c421-4d30-9b25-569995cb4057'	System	29 Mar 2021 13:25:47
User entered '29 Mar 2021 08:25:44'	System	29 Mar 2021 13:25:47



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-04-12T19:51:11-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '2625d7ee-95cf-4078-a0f9-2df2c655d103'	System	13 Apr 2021 00:51:26
User entered 'No (N)'	System	13 Apr 2021 00:51:26

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-04-12T19:51:18-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '2625d7ee-95cf-4078-a0f9-2df2c655d103'	System	13 Apr 2021 00:51:26
User entered 'No (N)'	System	13 Apr 2021 00:51:26



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-04-12T19:51:23-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '2625d7ee-95cf-4078-a0f9-2df2c655d103'	System	13 Apr 2021 00:51:26
User entered '12 Apr 2021 19:51:23'	System	13 Apr 2021 00:51:26

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-04-16T07:30:47-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7f42e646-d92e-499d-a009-e7b83833b564'	System	16 Apr 2021 12:30:57
User entered 'No (N)'	System	16 Apr 2021 12:30:57

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-04-16T07:30:50-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7f42e646-d92e-499d-a009-e7b83833b564'	System	16 Apr 2021 12:30:57
User entered 'No (N)'	System	16 Apr 2021 12:30:57

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-04-16T07:30:54-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '7f42e646-d92e-499d-a009-e7b83833b564' User entered '16 Apr 2021 07:30:54'	System	16 Apr 2021 12:30:57
	System	16 Apr 2021 12:30:57

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-04-23T07:47:55-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1f96646a-9aa0-47e2-a310-c7df95605e41'	System	23 Apr 2021 12:48:06
User entered 'No (N)'	System	23 Apr 2021 12:48:06

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-04-23T07:48:00-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1f96646a-9aa0-47e2-a310-c7df95605e41'	System	23 Apr 2021 12:48:06
User entered 'No (N)'	System	23 Apr 2021 12:48:06

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-04-23T07:48:03-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: '1f96646a-9aa0-47e2-a310-c7df95605e41'	System	23 Apr 2021 12:48:06
User entered '23 Apr 2021 07:48:03'	System	23 Apr 2021 12:48:06

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-05-02T12:00:54-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'e56015f2-f36f-4a02-9253-3c7c8cd8583f'	System	02 May 2021 17:01:48
User entered 'No (N)'	System	02 May 2021 17:01:48

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

Have you been exposed to someone with 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 (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-05-02T12:00:59-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'e56015f2-f36f-4a02-9253-3c7c8cd8583f'	System	02 May 2021 17:01:48
User entered 'No (N)'	System	02 May 2021 17:01:48

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-05-02T12:01:01-05:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'e56015f2-f36f-4a02-9253-3c7c8cd8583f' User entered '02 May 2021 12:01:01'	System	02 May 2021 17:01:48
	System	02 May 2021 17:01:48

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:44:51



**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:44:51



**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:44:51



**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:44:51



**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:44:51



**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:44:51



US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:44:51

**US3232157**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:11:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:44:51

US3232157

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:44:51
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:44:51

US3232157

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:11:01**

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 07:37:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-28T12:04:58-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b1b66606-5c77-446d-8a7b-0953576bc99c'	(b) (4), (b) (6) System	28 Feb 2021 18:08:57
User entered 'No (N)'	System	28 Feb 2021 18:08:57

US3232157

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:11:01

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:37:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2DDCEFA4-D3A5-4911-85C1-53F4F5CF9190)', Time: '2021-02-28T12:05:01-06:00', User OID: 'PatientReportedOutcome (US3232157)', ODM File OID: 'b1b66606-5c77-446d-8a7b-0953576bc99c'	(b) (4), (b) (6)	28 Feb 2021 18:08:57
User entered '28 Feb 2021 18:05:01'	System	28 Feb 2021 18:08:57

US3232157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 16:51:46
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	01 Dec 2020 16:50:33



US3232157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 16:51:46
User entered '1 Dec 2020'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	01 Dec 2020 16:50:33

US3232157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 16:51:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	01 Dec 2020 16:50:33

US3232157

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 16:51:46
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	01 Dec 2020 16:50:33

US3232157

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	05 Mar 2021 16:51:46
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	01 Dec 2020 16:50:24

US3232157

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:13:03
User entered 'I'	(b) (4), (b) (6) System	01 Dec 2020 16:50:24

US3232157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:06

US3232157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '05 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:06

US3232157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:06



US3232157

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:06

US3232157

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:11

US3232157

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User entered 'I'	(b) (4), (b) (6) System	04 Feb 2021 20:10:11

US3232157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:22

US3232157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '04 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:22

US3232157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:22

US3232157

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:22

US3232157

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	04 Feb 2021 20:10:27



US3232157

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User entered '1'	(b) (4), (b) (6) System	04 Feb 2021 20:10:27

US3232157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:50:11

US3232157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '04 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:50:11

US3232157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:50:11

US3232157

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:50:11

US3232157

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	30 Mar 2021 17:50:15

US3232157

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:34:46
User entered 'I'	(b) (4), (b) (6) System	30 Mar 2021 17:50:15

US3232157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:41
	(b) (4)	



US3232157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered '12 Apr 2021'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:41
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered 'Home (Home)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:41
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

---

Audit	User	Time (GMT)
User entered 'VISIT4'	System	14 Apr 2021 16:42:41

---

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:42:48

---

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	



US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:42:48

---

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:42:48

---

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:42:48

---



US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:24
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:48
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:42:48

---

US3232157

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:54
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:54
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:57
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:57
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:42:57
	(b) (4)	

US3232157

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

[Collection date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:42:57

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US3232157

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Apr 2021 16:43:01

US3232157

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 16:43:01

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US3232157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:23:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Apr 2021 17:20:54
	(b) (4)	

US3232157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 17:15:46
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirm as entered' (Site from System).	Rambod Rouhbakhsh (b) (4) Jerrica Sullivan (b) (4)	23 Apr 2021 15:23:45 22 Apr 2021 17:21:14
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	22 Apr 2021 17:20:54
User entered '21 Apr 2021'	Jerrica Sullivan (b) (4) (b) (4)	22 Apr 2021 17:20:54

US3232157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:23:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Jerrica Sullivan (b) (4)	22 Apr 2021 17:20:54
	(b) (4)	

US3232157

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:23:45
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Apr 2021 17:20:54

US3232157

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:23:45
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	22 Apr 2021 17:21:19
	(b) (4)	

US3232157

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 17:21:19

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US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:11:01

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:11:01

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '09:00'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:11:01

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:00
User entered '08 Jan 2021 09:00'	(b) (4), (b) (6) System	08 Jan 2021 21:56:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:11:01

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:11:01

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 1 (Day 1)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '06 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	11 Jan 2021 17:29:49
User entered '1'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	11 Jan 2021 17:29:49
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6)	11 Jan 2021 17:29:49
User entered empty.	System	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	11 Jan 2021 17:29:49
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:23

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 2 (Day 2)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '07 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	11 Jan 2021 17:29:49
User entered '1'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	11 Jan 2021 17:29:49
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6)	11 Jan 2021 17:29:49
User entered empty.	System	08 Jan 2021 21:59:54



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	11 Jan 2021 17:29:49
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:59:54

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 3 (Day 3)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '95'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98.3' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 22:00:32

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 4 (Day 4)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '09 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '94'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	11 Jan 2021 17:31:15

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '99.2' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:31:15

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 5 (Day 5)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '10 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '92'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98.6' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:32:42

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 6 (Day 6)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	12 Jan 2021 14:04:09



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98.6' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 14:04:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 7 (Day 7)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '94'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98.2' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	13 Jan 2021 14:49:58

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 8 (Day 8)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '13 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '95'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98.0' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Jan 2021 14:12:11

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 9 (Day 9)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '14 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97.6' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:56:30

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 10 (Day 10)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '15 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '96'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 15:59:52



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98.6' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:59:52

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 12 (Day 12)'	(b) (4) Jerrica Sullivan (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '16 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '99.4' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:10:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 13 (Day 13)'	(b) (4) Jerrica Sullivan (b) (4)	22 Jan 2021 16:16:10



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '17 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '99.0' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:16:10

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 14 (Day 14)'	(b) (4) Jerrica Sullivan (b) (4)	22 Jan 2021 16:17:09

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '18 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '99'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98.0' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09



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Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:17:09

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 15 (Day 15)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '19 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '100'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 16:18:39



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97.7' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:18:39

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 16 (Day 16)'	(b) (4) Jerrica Sullivan (b) (4)	22 Jan 2021 16:24:26

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '20 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '100'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97.9' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:24:26

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 17 (Day 17)'	(b) (4) Jerrica Sullivan (b) (4)	22 Jan 2021 16:25:21



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '21 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '99'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '96.7' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 16:25:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 18 (Day 18)'	(b) (4) Adreanna Pou (b) (4)	25 Jan 2021 17:10:43

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '22 Jan 2021'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '96'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '99.5' F	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:10:43

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 19 (Day 19)'	(b) (4) Adreanna Pou (b) (4)	25 Jan 2021 17:12:03
	(b) (4)	

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Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '23 Jan 2021'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '95'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	25 Jan 2021 17:12:03



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98.3' F	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:12:03

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 20 (Day 20)'	(b) (4) Adreanna Pou (b) (4)	25 Jan 2021 17:13:21
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '24 Jan 2021'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97.9' F	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Severe (Severe)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	25 Jan 2021 17:13:21

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 21 (Day 21)'	(b) (4) Adreanna Pou (b) (4)	27 Jan 2021 21:28:51



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '25 Jan 2021'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97.5' F	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:28:51

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 21 (Day 21)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 22 (Day 22)'	(b) (4) Adreanna Pou (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '26 Jan 2021'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97.7' F	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37



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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	27 Jan 2021 21:32:37

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 22 (Day 22)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 23 (Day 23)'	(b) (4) Jerrica Sullivan (b) (4)	28 Jan 2021 13:51:56

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '27 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '99'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	28 Jan 2021 13:51:56



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97.5' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	28 Jan 2021 13:51:56

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Day 23 (Day 23)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 12:43:03
User entered 'Day 24 (Day 24)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '28 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '99'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
User entered '%'	(b) (4), (b) (6) System	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97.7' F	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Mild (Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Moderate (Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:11:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:14
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'None (None)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	29 Jan 2021 15:23:22

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:11:01

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	27 Jan 2021 10:36:32
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F60HMA, accession number of processed samples. shipping date 08Jan2021, tracking number unavailable ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	26 Jan 2021 14:36:23
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08JAN2021 is recorded under Covid-19 Assessment in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 11:52:56
User entered '08 Jan 2021'	Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:24



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:11:01

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:24

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:11:01

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
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) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 12:56:21
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'confirmed ' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 15:53:24
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 15:53:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Jan 2021 15:53:15
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	12 Jan 2021 15:53:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 15:53:15
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 21:56:24
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:24

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Folder: Covid-19 Assessment 08 Jan 2021

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:24

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:11:01

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:24

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:11:01

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:24

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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)	29 Apr 2021 20:19:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:24

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Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:11:01

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:24

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:24



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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:22
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 15:53:15

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Generated On: 09 Jun 2021 16:11:01

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46



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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	21 Jan 2021 21:50:49
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	21 Jan 2021 21:50:49
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	21 Jan 2021 21:50:49
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '92' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	21 Jan 2021 21:50:49
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46



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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Form: Covid-19 Severity Assessment

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46



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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	Jerrica Sullivan (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46



US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:11:01

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:14:46

US3232157

Folder: Covid-19 Assessment 08 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:11:01

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:19:35
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 14:41:41
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Mar 2021 20:44:02

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:11:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:33:33

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:11:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:55
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:33:33

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:11:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User entered '10 Jan 2021'	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	



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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:11:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:33:33

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:11:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Jan 2021 14:50:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Jan 2021 14:50:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	13 Jan 2021 14:50:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 17:33:33
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:11:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User entered '12 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	13 Jan 2021 14:50:30
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:11:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:33:33

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:11:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 16:25:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 16:25:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Jan 2021 16:25:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 17:33:33
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:11:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User entered '14 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Jan 2021 16:25:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:11:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:33:33

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:11:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 16:25:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 16:25:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Jan 2021 16:25:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 17:33:33
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	



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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:11:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User entered '16 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Jan 2021 16:25:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:11:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:33:33

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:11:01

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 16:25:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 16:25:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Jan 2021 16:25:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 17:33:33
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:11:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User entered '21 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	22 Jan 2021 16:25:58
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:11:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:33:33

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:11:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 15:19:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 15:19:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	29 Jan 2021 15:19:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 17:33:33
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:11:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User entered '28 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	29 Jan 2021 15:19:14
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:11:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jerrica Sullivan (b) (4) (b) (4)	11 Jan 2021 17:33:33



US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:11:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 19:09:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 19:09:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	05 Feb 2021 19:09:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 17:33:33
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

US3232157

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:11:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 20:06:55
	(b) (4), (b) (6)	
User entered '05 Feb 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	05 Feb 2021 19:09:12
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	11 Jan 2021 17:33:33
	(b) (4)	

US3232157

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:00
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:37

US3232157

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:00
User entered '08 Jan 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:37

US3232157

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[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 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:56:37

US3232157

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User entered 'SICKD1'	(b) (4), (b) (6) System	08 Jan 2021 21:56:37

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered '08 Jan 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50



US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered '09:17'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User entered '08 Jan 2021 09:17'	(b) (4), (b) (6) System	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6) System	08 Jan 2021 21:58:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	08 Jan 2021 21:58:08
User entered '179' cm reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:58:08
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Jan 2021 21:57:50
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50
DataPoint set to visible.	System	08 Jan 2021 21:56:37

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered '80.29' kg	(b) (4), (b) (6) Jerrica Sullivan (b) (4)	08 Jan 2021 21:57:50
DataPoint set to visible.	(b) (4) System	08 Jan 2021 21:56:37

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered '98.3' F	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered 'Oral (Oral)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered '64'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50



US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User entered 'bpm'	(b) (4), (b) (6) System	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered '22'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User entered 'breaths/min'	(b) (4), (b) (6) System	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered '140'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User entered 'mmHg'	(b) (4), (b) (6) System	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:05
User entered '91'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User entered 'mmHg'	(b) (4), (b) (6) System	08 Jan 2021 21:57:50

US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 21:40:06



US3232157

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 21:40:06

US3232157

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:14
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:58:17

US3232157

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:14
User entered '08 Jan 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:58:17

US3232157

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:11:01

[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 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:20
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:58:36

US3232157

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:11:01

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:40:06
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:20
User entered '08 Jan 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Jan 2021 21:58:36

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:08
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:27
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:09

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:08
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:27
User entered '05 Feb 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:09

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[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 21:25:08
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:09



US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:08
User entered 'SICKD28'	(b) (4), (b) (6) System	05 Feb 2021 19:08:09

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered '05 Feb 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered '08:30'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User entered '05 Feb 2021 08:30'	(b) (4), (b) (6) System	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered '178' cm	(b) (4), (b) (6) Jerrica Sullivan (b) (4)	05 Feb 2021 19:08:56
DataPoint set to visible.	(b) (4) System	05 Feb 2021 19:08:09

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered '76.9' kg	(b) (4), (b) (6) Jerrica Sullivan (b) (4)	05 Feb 2021 19:08:56
DataPoint set to visible.	(b) (4) System	05 Feb 2021 19:08:09

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered '98.3' F	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56



US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered 'Oral (Oral)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered '64'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User entered 'bpm'	(b) (4), (b) (6) System	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered '20'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User entered 'breaths/min'	(b) (4), (b) (6) System	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered '99'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User entered 'mmHg'	(b) (4), (b) (6) System	05 Feb 2021 19:08:56



US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:32
User entered '63'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
User entered 'mmHg'	(b) (4), (b) (6) System	05 Feb 2021 19:08:56

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
	(b) (4), (b) (6)	

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:04
	(b) (4), (b) (6)	

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:00
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:40
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:17

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:25:00
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:40
User entered '05 Feb 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:17

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:11:01

[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 21:24:57
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:46
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:25

US3232157

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:11:01

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:57
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:06:46
User entered '05 Feb 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Feb 2021 19:08:25



US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:51:39

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:51:39

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[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 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Clinic (Clinic)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:51:39

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	11 Feb 2021 15:51:39

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4)	09 Mar 2021 14:53:44
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 14:53:50

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:53:07
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Jerrica Sullivan (b) (4)	09 Mar 2021 14:53:44
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 14:53:50



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Placebo (Placebo)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Placebo (Placebo)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Placebo (Placebo)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:53:07
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '1'	(b) (4), (b) (6) System	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:01

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '1'	(b) (4), (b) (6) System	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done.	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done.	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
	(b) (4), (b) (6)	
User entered empty.	System	11 Feb 2021 15:54:31
DataPoint set to visible.	System	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done.	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done.	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
	(b) (4), (b) (6)	
User entered empty.	System	11 Feb 2021 15:54:31
DataPoint set to visible.	System	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08:41'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '11 Feb 2021 08:41'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '98.3' F	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (Oral)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '59'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'bpm'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '20'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31



US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '107'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'mmHg'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '70'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'mmHg'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done.	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered missing code ND - Not Done.	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:54:31
DataPoint set to visible.	System	11 Feb 2021 15:53:07



US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '09:27'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '11 Feb 2021 09:27'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '97.5' F	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Other (Other)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'temporal'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	



US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '58'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'bpm'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '22'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:54:31
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '115'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'mmHg'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '83'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:54:31

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'mmHg'	(b) (4), (b) (6) System	11 Feb 2021 15:54:31



US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:53:15
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:53:15

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:53:36
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:53:36

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

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 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:53:36

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'mRNA-1273'	(b) (4), (b) (6)	11 Feb 2021 15:53:36
DataPoint set to visible.	System	11 Feb 2021 15:53:07

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:53:36

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '09:15'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:53:36
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '11 Feb 2021 09:15'	(b) (4), (b) (6) System	11 Feb 2021 15:53:36

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:53:36
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'ONCE'	(b) (4), (b) (6) System	11 Feb 2021 15:53:36

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	11 Feb 2021 15:53:36

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:51:49
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:51:49

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08:48'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:51:49

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '11 Feb 2021 08:48'	(b) (4), (b) (6) System	11 Feb 2021 15:51:49



US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:52:06
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:52:06

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08:43'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	11 Feb 2021 15:52:06

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:01

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '11 Feb 2021 08:43'	(b) (4), (b) (6) System	11 Feb 2021 15:52:06

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	11 Feb 2021 15:53:20
	(b) (4)	

US3232157

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:19:55
User entered '1'	(b) (4), (b) (6) System	11 Feb 2021 15:53:20

US3232157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 10:11:26
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:35:12

US3232157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 10:11:26
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '18 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:35:12



US3232157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 10:11:26
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:35:12

US3232157

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 10:11:26
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:35:12

US3232157

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 10:11:26
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:35:18

US3232157

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 10:11:26
User entered '1'	(b) (4), (b) (6) System	18 Feb 2021 17:35:18

US3232157

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 10:11:26
User entered '1'	(b) (4), (b) (6) System	18 Feb 2021 17:35:18
DataPoint set to visible.	System	18 Feb 2021 17:35:18

US3232157

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:09
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered '16 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:09
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'Home (Home)'	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:09
	(b) (4)	



US3232157

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered 'OLD29'	(b) (4), (b) (6) System	14 Apr 2021 16:40:09

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	



US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	



US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	



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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

US3232157

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:19
	(b) (4)	



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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:19

US3232157

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Apr 2021 16:40:28

US3232157

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:28
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:33
	(b) (4)	

US3232157

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	14 Apr 2021 16:44:03
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	14 Apr 2021 16:44:03
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	14 Apr 2021 16:40:33
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	14 Apr 2021 16:40:33

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

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)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:33
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
	(b) (4), (b) (6)	
User entered empty.	System	14 Apr 2021 16:40:33
DataPoint set to visible.	System	18 Feb 2021 17:35:18

US3232157

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:33
	(b) (4)	



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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:33
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:33

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:33
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:33

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered empty.	(b) (4), (b) (6) System	14 Apr 2021 16:40:33

US3232157

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	14 Apr 2021 16:40:48
	(b) (4)	

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:34:54
User entered '1'	(b) (4), (b) (6) System	14 Apr 2021 16:40:48

US3232157

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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 DM). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:50:38
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' answered with 'inadvertently missed' (Site from DM). 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 DM).	Rambod Rouhbakhsh (b) (4) Jerrica Sullivan (b) (4) (b) (4)	23 Apr 2021 15:23:45 21 Apr 2021 16:25:29 21 Apr 2021 16:15:39
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.' canceled (Site from System). 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). User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) System Jerrica Sullivan (b) (4) (b) (4)	21 Apr 2021 16:15:33 14 Apr 2021 16:41:51 14 Apr 2021 16:41:51



US3232157

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:23:45
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:41:51
	(b) (4)	

US3232157

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:23:45
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	14 Apr 2021 16:41:51

US3232157

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:23:45
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	(b) (4)	14 Apr 2021 20:03:45
User entered 'call not completed, patient requested due to health reasons' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	14 Apr 2021 20:03:45
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	14 Apr 2021 16:41:51
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:41:51

US3232157

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:41:56
	(b) (4)	

US3232157

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:01

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 16:41:56

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US3232157

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:21
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered '12 Apr 2021'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:21
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'Home (Home)'	(b) (4)	
	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:21
	(b) (4)	



US3232157

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:01

[Folder OID](#)

---

Audit	User	Time (GMT)
User entered 'OLD57'	System	14 Apr 2021 16:45:21

---

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Vital Signs Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:45:27

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US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	



US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:45:27

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US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:45:27

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US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:45:27

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US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:27
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:01

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:45:27

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US3232157

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:31
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:31
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:34
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:34
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	14 Apr 2021 16:45:34
	(b) (4)	

US3232157

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:01

[Collection date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 16:45:34

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US3232157

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:11:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:35
User signature succeeded.	(b) (4), (b) (6)	12 Mar 2021 19:57:22
User entered 'Yes (Y)'	Rambod Rouhbakhsh	12 Jan 2021 18:12:58
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:51
User entered 'USA-US105-2021-mRNA-1273-P301000001'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24
User entered 'New'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 21:40:24



US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Jan 2021 18:15:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:15:03
Data point term sent to Coder	System	12 Jan 2021 18:14:40
User entered 'COVID-19'	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
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.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	07 Mar 2021 16:56:35
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) (b) (4), (b) (6)	07 Mar 2021 16:55:41
User closed query 'PV Query: Please consider updating event start date to 06 Jan 2021 as it was when the subject first experienced symptoms.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 21:43:04
Query 'PV Query: Please consider updating event start date to 06 Jan 2021 as it was when the subject first experienced symptoms.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 23:16:17
User entered '06 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 23:16:11
User opened query 'PV Query: Please consider updating event start date to 06 Jan 2021 as it was when the subject first experienced symptoms.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Jan 2021 15:57:33
User entered '08 Jan 2021'	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	12 Jan 2021 18:13:44

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US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	09 Feb 2021 14:23:21
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	12 Jan 2021 18:13:44



US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '05 Feb 2021' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	12 Feb 2021 17:18:23
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	09 Feb 2021 14:23:21
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) (b) (4), (b) (6)	02 Feb 2021 21:43:12
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 'ongoing' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 23:16:31
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) (b) (4), (b) (6)	20 Jan 2021 15:57:03
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	12 Jan 2021 18:13:44

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US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	22 Jan 2021 15:53:31
User entered 'Grade 4 (Grade 4)'	(b) (4) Jerrica Sullivan (b) (4)	12 Jan 2021 18:13:44
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4) System	22 Jan 2021 15:53:31
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	22 Jan 2021 15:53:31
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	12 Jan 2021 18:13:44
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44



US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Not Related (NOT RELATED)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44



US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Not Related (NOT RELATED)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User closed query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 21:43:27
Query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 23:16:38
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	22 Jan 2021 15:53:31
User opened query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	20 Jan 2021 19:04:21
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '1'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
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.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	07 Mar 2021 16:56:45
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) (b) (4), (b) (6)	07 Mar 2021 16:56:15
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 14:23:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 14:23:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Feb 2021 14:23:21
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) (b) (4), (b) (6)	02 Feb 2021 21:43:43
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 'ongoing' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	27 Jan 2021 23:16:45
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) (b) (4), (b) (6)	20 Jan 2021 15:57:18
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 18:13:44
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44

US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:13:44



US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	12 Jan 2021 18:13:44

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US3232157

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	12 Jan 2021 18:13:44

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US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Feb 2021 00:37:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Feb 2021 00:37:04
Data point term sent to Coder	System	18 Feb 2021 18:15:10
Coding entries removed.	Adreanna Pou (b) (4) (b) (4)	18 Feb 2021 18:14:15
User entered 'new onset gastroenteritis' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	18 Feb 2021 18:14:15
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 17:33:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Feb 2021 17:33:52
Data point term sent to Coder	System	18 Feb 2021 17:33:20
User entered 'irritable bowel syndrome'	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '10 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22



US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 17:32:22

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US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 17:32:22

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US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22



US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22



US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	18 Feb 2021 18:14:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:14:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	18 Feb 2021 18:14:15
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:32:22
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	18 Feb 2021 18:14:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:14:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	18 Feb 2021 18:14:15
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:32:22
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '1'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	11 Mar 2021 21:59:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Mar 2021 21:59:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Adreanna Pou (b) (4) (b) (4)	11 Mar 2021 21:59:37
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:32:22
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22



US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:32:22

US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	18 Feb 2021 17:32:22

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US3232157

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 17:32:22

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US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:34:06
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. answered with 'this was apart of the illness visit and patient was positive for covid ' (Site from DM).	Jerrica Sullivan (b) (4)	26 Mar 2021 18:38:21
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection. (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:53:04
User signature succeeded.	Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	22 Feb 2021 15:54:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Feb 2021 15:54:59
Data point term sent to Coder	System	22 Feb 2021 15:54:19
User entered 'cough'	Jerrica Sullivan (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User closed query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 17:00:23
Query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	02 Mar 2021 13:38:37
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	02 Mar 2021 13:38:27
User opened query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 16:14:02
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10



US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '06 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 15:54:10

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US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '05 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 15:54:10

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US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10



US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	22 Feb 2021 15:54:10
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10



US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Not Related (NOT RELATED)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Not Related (NOT RELATED)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '1'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10



US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	12 Mar 2021 19:57:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	22 Feb 2021 15:54:10

US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	22 Feb 2021 15:54:10

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US3232157

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 15:54:10

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US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Investigations, HLT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Transaminases increased, LLT: Transaminitis - version MedDRA\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	25 Mar 2021 15:31:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:31:28
Data point term sent to Coder	System	25 Mar 2021 15:30:59
User entered 'transaminitis'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00



US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '12 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:30:00

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US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '13 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00



US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:30:00

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US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00



US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00



US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
Query 'Per CDM RQ: Response noted, however there is no Concomitant Medication recorded that matches this AE during this timeframe. kindly update Action Taken = None, else clarify.' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 14:12:20
User opened query 'Per CDM RQ: Response noted, however there is no Concomitant Medication recorded that matches this AE during this timeframe. kindly update Action Taken = None, else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 13:52:18
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 13:52:18
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:19:39
User entered '0' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:19:25
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:04:57
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 13:43:52
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:20:36
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:04:37
User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 15:31:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 15:31:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Mar 2021 15:31:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Mar 2021 15:30:00
User entered empty.	System	25 Mar 2021 15:30:00
	Jerrica Sullivan (b) (4)	25 Mar 2021 15:30:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:30:00

US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:30:00

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US3232157

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:30:00

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	25 Mar 2021 15:32:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:32:27
Data point term sent to Coder	System	25 Mar 2021 15:32:00
User entered 'Worsening Gastroesophageal reflux disease'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '12 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:31:16

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '13 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:31:16

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US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '1'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM). Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 13:54:20
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM). User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:20:45
	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:05:12
	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:31:16

US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
	(b) (4), (b) (6)	
User entered 'EGD 12MAR2021' reason for change:	Jerrica Sullivan (b) (4)	05 Apr 2021 16:29:46
Data Entry Error	(b) (4)	
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 15:31:16
	(b) (4)	



US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:31:16

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US3232157

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:31:16

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US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Early satiety, LLT: Early satiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:33:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:33:28
Data point term sent to Coder	System	25 Mar 2021 15:33:01
User entered 'early satiety'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '12 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36



US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:32:36

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US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '13 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:32:36

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US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36



US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36



US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '1'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 13:56:34
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:20:52
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:05:20
User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36



US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:32:36

US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:32:36

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US3232157

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:32:36

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US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Hepatobiliary disorders, HLGT: Bile duct disorders, HLT: Obstructive bile duct disorders (excl neoplasms), PT: Bile duct obstruction, LLT: Bile duct obstruction - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	26 Mar 2021 09:44:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 09:44:41
Data point term sent to Coder	System	25 Mar 2021 15:34:02
User entered 'biliary obstruction'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26



US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '12 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:33:26

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US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '13 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:33:26

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US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4)	25 Mar 2021 15:33:26
	(b) (4)	



US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26



US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '1'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26



US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 13:57:17
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:20:58
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:05:27
User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:33:26

US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:33:26

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US3232157

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:33:26

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US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	25 Mar 2021 15:37:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:37:28
Data point term sent to Coder	System	25 Mar 2021 15:37:13
User entered 'sepsis'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33



US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '12 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:36:33

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US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '13 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33



US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:36:33

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US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4)	25 Mar 2021 15:36:33
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33



US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33



US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '1'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 13:58:32
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:21:06
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:05:38
User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:36:33

US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:36:33

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US3232157

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:36:33

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US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Pancreatic neoplasms malignant (excl islet cell and carcinoid), PT: Pancreatic carcinoma, LLT: Pancreatic cancer - version MedDRA\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	07 Apr 2021 14:41:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:41:41
User closed query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 13:59:14
Data point term sent to Coder	System	05 Apr 2021 16:22:18
Query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.'	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:21:46
answered with 'UPDATED' (Site from DM). Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:21:41
User entered 'PANCREATIC MASS (MALIGNANT/CANCEROUS)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:21:41
User opened query 'Per DM CLR: Please update the condition to confirm if the Mass was benign or cancerous. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:05:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Pancreatic disorders NEC, PT: Pancreatic mass, LLT: Pancreatic mass - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:38:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:38:28

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	25 Mar 2021 15:38:14
User entered 'pancreatic mass'	Jerrica Sullivan (b) (4)	25 Mar 2021 15:37:43
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '26 Feb 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:37:43

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US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:37:43

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US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 13:34:28
Query 'Per MM: please confirm seriousness assessment. ' answered with 'confirm correct as entered' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	26 Apr 2021 13:40:19
User opened query 'Per MM: please confirm seriousness assessment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 00:12:29
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43



US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43



US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 14:02:45
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UDPATED FENTANYL' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:22:20
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:05:59
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 14:01:08
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:21:55
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:06:10
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per CDM - RQ: Response noted. Field should be filled as per CCG's. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 10:34:50
Query 'Per CDM - RQ: Response noted. Field should be filled as per CCG's. Please review and update accordingly. Else clarify.' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	02 Apr 2021 16:01:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	02 Apr 2021 16:01:12
User opened query 'Per CDM - RQ: Response noted. Field should be filled as per CCG's. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 09:35:54
User closed query 'Per CDM: Response noted. However please select "Not Recovered/Not Resolved" or Recovering/Resolving" from the dropdown list if AE still ongoing. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 09:35:54
Query 'Per CDM: Response noted. However please select "Not Recovered/Not Resolved" or Recovering/Resolving" from the dropdown list if AE still ongoing. Please review and update accordingly. Else clarify.' answered with 'patient has not recovered as well as not recovering at this time. treatment for mass has not began yet' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	26 Mar 2021 12:49:23
User opened query 'Per CDM: Response noted. However please select "Not Recovered/Not Resolved" or Recovering/Resolving" from the dropdown list if AE still ongoing. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Mar 2021 08:26:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Mar 2021 08:22:37
Query 'Data is required. Please complete.' answered with 'this is an ongoing ae at this time' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:56

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:37:43
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43



US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:37:43

US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:37:43

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US3232157

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:37:43

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US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: General disorders and administration site conditions, HLT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	25 Mar 2021 15:40:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:40:28
Data point term sent to Coder	System	25 Mar 2021 15:40:16
User entered 'fever'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36



US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) System	25 Mar 2021 15:39:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 15:39:52
User entered '11 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:52
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:39:36
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:39:36

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US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) System	25 Mar 2021 15:39:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 15:39:52
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:52
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:39:36
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	25 Mar 2021 15:39:52
User entered '13 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Mar 2021 15:39:52
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	25 Mar 2021 15:39:36
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:39:36

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US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36



US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36



US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	25 Mar 2021 15:39:36
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '1'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36



US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:39:36

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:39:36

---

US3232157

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:39:36

---

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Hepatobiliary disorders, HLG: Bile duct disorders, HLT: Bile duct infections and inflammations, PT: Cholangitis, LLT: Cholangitis - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4)	25 Mar 2021 15:41:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:41:29
Data point term sent to Coder	System	25 Mar 2021 15:41:17
User entered 'cholangitis'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47



US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '12 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:40:47

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US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '13 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47



US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:40:47

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US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47



US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	25 Mar 2021 15:40:47
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	Jerrica Sullivan (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47



US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '1'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM). Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 14:04:00
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM). User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:23:05
	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:02:53
	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:40:47

US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:40:47

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US3232157

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:40:47

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US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	25 Mar 2021 16:02:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:02:29
Data point term sent to Coder	System	25 Mar 2021 15:46:28
User entered 'abdominal pain'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '07 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:45:29

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US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29



US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:45:29

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US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) System	25 Mar 2021 15:45:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 15:45:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:36
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:45:29
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29



US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29



US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '1'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	06 Apr 2021 14:04:40
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:23:16
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. '(Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 06:03:05
User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per CDM - RQ: Response noted. Field should be filled as per CCG's. Please review and update accordingly. Else clarify' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 10:35:32
Query 'Per CDM - RQ: Response noted. Field should be filled as per CCG's. Please review and update accordingly. Else clarify' answered with 'UPDATED' (Site from DM).	Jerrica Sullivan (b) (4)	02 Apr 2021 16:03:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Apr 2021 16:03:18
User opened query 'Per CDM - RQ: Response noted. Field should be filled as per CCG's. Please review and update accordingly. Else clarify' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:38:14
User closed query 'Per CDM: Response noted. However please select "Not Recovered/Not Resolved" or Recovering/Resolving" from the dropdown list if AE still ongoing. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:38:14
Query 'Per CDM: Response noted. However please select "Not Recovered/Not Resolved" or Recovering/Resolving" from the dropdown list if AE still ongoing. Please review and update accordingly. Else clarify.' answered with 'patient has not recovered from pain as well as not recovering as treatment for mass has not began yet ' (Site from DM).	Jerrica Sullivan (b) (4)	26 Mar 2021 12:50:13
User opened query 'Per CDM: Response noted. However please select "Not Recovered/Not Resolved" or Recovering/Resolving" from the dropdown list if AE still ongoing. Please review and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:27:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 08:26:59
Query 'Data is required. Please complete.' answered with 'this is an ongoing ae at this time ' (Site from System).	Jerrica Sullivan (b) (4)	25 Mar 2021 15:45:55
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29



US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:45:29

US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 15:45:29

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US3232157

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:45:29

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US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	05 Apr 2021 19:30:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 19:30:18
Data point term sent to Coder	System	05 Apr 2021 19:26:54
User entered 'insomnia'	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
	(b) (4), (b) (6)	
User entered '11 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Apr 2021 13:41:33
	(b) (4)	
User entered '12 Mar 2021'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:26:51
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:26:51

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US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 19:26:51

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US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
	(b) (4), (b) (6)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4)	05 Apr 2021 19:26:51
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51



US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51



US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'None (NONE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '1'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51



US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 19:26:51

US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 19:26:51

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US3232157

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:26:51

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US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 21:27:04
User entered 'USA-US105-2021-mRNA-1273-P301000008'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01
User entered 'New'	(b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 21:27:01

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Gastrointestinal neoplasms malignant and unspecified, HLT: Pancreatic neoplasms malignant (excl islet cell and carcinoid), PT: Pancreatic carcinoma metastatic, LLT: Pancreatic cancer metastatic - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	08 Apr 2021 21:33:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 21:33:48
Data point term sent to Coder	System	08 Apr 2021 17:17:42
User entered 'metastatic pancreatic cancer'	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58



US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '22 Mar 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 17:16:58

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US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.â€ Please leave query open until information is available.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 13:23:04
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 14:06:25
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58



US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 17:16:58

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US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4), (b) (6) System	08 Apr 2021 17:17:23
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	08 Apr 2021 17:16:58
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
	(b) (4), (b) (6)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Apr 2021 17:17:23
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	08 Apr 2021 17:17:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	08 Apr 2021 17:16:58
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58



US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4)	08 Apr 2021 17:17:23
	(b) (4)	
User entered 'No (N)'	Jerrica Sullivan (b) (4)	08 Apr 2021 17:16:58
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
	(b) (4), (b) (6)	
User entered '1' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Apr 2021 17:17:23
	(b) (4)	
User entered '0'	Jerrica Sullivan (b) (4)	08 Apr 2021 17:16:58
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 19:54:21
User entered 'None (NONE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 19:23:32
User closed query 'PV Query: As subject only received 1 dose of mRNA-1273, please update action taken with study drug from none to dose delayed. If subject is expected to not receive both doses, please state so with reason and update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 18:52:22
Query 'PV Query: As subject only received 1 dose of mRNA-1273, please update action taken with study drug from none to dose delayed. If subject is expected to not receive both doses, please state so with reason and update action taken to withdrawn.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 15:01:26
DataPoint Un-verified.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 15:01:06
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 15:01:06
User opened query 'PV Query: As subject only received 1 dose of mRNA-1273, please update action taken with study drug from none to dose delayed. If subject is expected to not receive both doses, please state so with reason and update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:12:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:39:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 20:39:58
User entered 'None (NONE)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:58
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 17:19:32
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:19:32
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58



US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Per CDM: Other action taken is Concomitant Medication however, there is no corresponding Concomitant Medication record(s) for 'METASTATIC PANCREATIC CANCER'. If CM is already recorded, please provide log line number ensuring, indication matches with this event. Please review and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 14:44:18
Query 'Per CDM: Other action taken is Concomitant Medication however, there is no corresponding Concomitant Medication record(s) for 'METASTATIC PANCREATIC CANCER'. If CM is already recorded, please provide log line number ensuring, indication matches with this event. Please review and reconcile accordingly.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:30:54
User opened query 'Per CDM: Other action taken is Concomitant Medication however, there is no corresponding Concomitant Medication record(s) for 'METASTATIC PANCREATIC CANCER'. If CM is already recorded, please provide log line number ensuring, indication matches with this event. Please review and reconcile accordingly.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 17:48:52
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 15:27:30
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'sent via email ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	16 Apr 2021 18:02:43
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 14:06:01
User entered 'I'	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 14:05:40
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 20:39:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 20:39:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:58
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 17:16:58
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: If available, please provide results of CT scan of chest, abdomen, and pelvis from 26 Feb 2021.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:44:16
User closed query 'PV Query: If available, please provide confirmation of results of peritoneal implants collected from laparoscopic biopsy from 25 Mar 2021.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:44:14
User closed query 'PV Query: If available, please provide any significant findings from appointment from 20 Apr 2021 appointment stated in laboratory documents.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:44:12
Query 'PV Query: If available, please provide confirmation of results of peritoneal implants collected from laparoscopic biopsy from 25 Mar 2021.' answered with 'Positive for adenocarcinoma with mucinous features.' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 19:51:23
Query 'PV Query: If available, please provide any significant findings from appointment from 20 Apr 2021 appointment stated in laboratory documents.' answered with 'He was treated with 1 cycle of modified FOLFIRINOX and had very poor tolerance with severe nausea and vomiting, cachexia, weakness, and fatigue. He was essentially in the bed for the last 2 weeks. He has lost 15 pounds in the last 2 weeks. However, he was able to gain 2 pounds back in the last few days. He has required IV fluids almost daily. He is still very weak. He is improving on a gluten-free diet.  I held treatment so that he could recover a bit and initiate Gemzar and Abraxane today. I felt he was not a candidate for any further FOLFIRINOX given the severity of the toxicities. He is feeling better and has gained 2 lbs. No nausea or vomiting. ECOG PS=1.  63-year-old white male with metastatic pancreatic adenocarcinoma with very poor tolerance of modified FOLFIRINOX. I would allow him to recover for a week and I think that he would be a better candidate for Gemzar and Abraxane.  ' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 19:49:34

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
<p>Query 'PV Query: If available, please provide results of CT scan of chest, abdomen, and pelvis from 26 Feb 2021.' answered with 'abdomen and pelvis= Markedly abnormal appearance of the body and tail of the pancreas as described above. The head and neck of the pancreas have a more normal appearance and the dilatation of the pancreatic duct begins at the junction of the neck and body. Peripancreatic, &lt;br /&gt;para-aortic, retrocrural, and mesenteric nodes disseminated throughout the abdomen. Note is also made of some involvement by tumor of the splenic artery and vein as well as a small portion of the proximal portal vein&lt;br /&gt; &lt;br /&gt;Small amount of ascites around the liver, spleen, paracolic gutters and the pelvis. There is concern for peritoneal seeding with nodular density seen along the peritoneal reflections of the upper abdomen bilaterally.&lt;br /&gt; &lt;br /&gt;Diffuse thickening of the walls of the stomach and pyloric channel and duodenum noted with a soft tissue mass or lymphadenopathy along the posterior margins of the distal stomach and head and neck of the pancreas&lt;br /&gt; &lt;br /&gt;Overall findings suggest primary pancreatic neoplasm with disseminated metastatic disease. This may be amenable to endoscopic ultrasound and biopsy for tissue diagnosis.&lt;br /&gt; &lt;br /&gt;The findings were discussed with (b) (6) in gastroenterology.&lt;br /&gt; &lt;br /&gt;This CT examination was performed using one or more of the following dose reduction techniques: Automated exposure control, adjustment of the mA and/or kv according to patient size, use of iterative reconstructive techniques.&lt;br /&gt;&lt;br /&gt;Chest= Masslike density in the right middle lobe is relatively low in attenuation and could represent loculated pleural fluid collection, pneumonia, or sequela of an infectious process. A mass, and in particular, a metastasis is considered less likely. &lt;br /&gt;Bronchoscopy may be the helpful in further evaluation.&lt;br /&gt; &lt;br /&gt;Several pulmonary nodules in both lower lungs identified suspicious for metastatic disease.&lt;br /&gt; &lt;br /&gt;Scattered small</p>	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 19:39:51

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
groundglass opacities bilaterally most likely sequela of recent COVID pneumonitis' (Site from Safety).		
User opened query 'PV Query: If available, please provide any significant findings from appointment from 20 Apr 2021 appointment stated in laboratory documents.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:13:13
User opened query 'PV Query: If available, please provide confirmation of results of peritoneal implants collected from laparoscopic biopsy from 25 Mar 2021.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:13:04
User opened query 'PV Query: If available, please provide results of CT scan of chest, abdomen, and pelvis from 26 Feb 2021.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:12:56
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User closed query 'Please confirm date of mRNA-1273 administration as Additional source narrative states administered on 02 Feb 2021, but was provided as 11 Feb 2021.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 15:27:34
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [11 Feb 2021], then event occurred).' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 15:27:32
Query 'Please confirm date of mRNA-1273 administration as Additional source narrative states administered on 02 Feb 2021, but was provided as 11 Feb 2021.' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	16 Apr 2021 14:18:22
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [11 Feb 2021], then event occurred).' answered with 'updated' (Site from Safety).	Jerrica Sullivan (b) (4) (b) (4)	16 Apr 2021 14:18:06



US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS A 63 YEAR OLD MALE WHO RECEIVED HIS FIRST AND ONLY DOSE OF THE MRNA-1273-P301 TRIAL VACCINE ON 11 FEB 2021 AND WAS ULTIMATELY DIAGNOSED WITH METASTATIC PANCREATIC ADENOCARCINOMA WITH PERITONEAL IMPLANTS AND POSSIBLE PULMONARY METASTASES ON 30 MAR 2021.' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	16 Apr 2021 14:17:47
User opened query 'Please confirm date of mRNA-1273 administration as Additional source narrative states administered on 02 Feb 2021, but was provided as 11 Feb 2021.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 14:07:15
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on [11 Feb 2021], then event occurred).' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 14:06:58
User entered 'Subject is a 63 year old male who received his first and only dose of the MRNA-1273-P301 trial vaccine on 02 Feb 2021 and was ultimately diagnosed with metastatic pancreatic adenocarcinoma with peritoneal implants and possible pulmonary metastases on 30 Mar 2021.' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 18:13:22
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:16:58

US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 17:16:58

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US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 17:16:58

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US3232157

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

---

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 17:16:58

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US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Lung infiltration, LLT: Pulmonary infiltration - version MedDRA\\23.0.	Coder Import (b) (4)	11 Apr 2021 19:27:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Apr 2021 19:27:34
Data point term sent to Coder	System	09 Apr 2021 20:39:39
User entered 'pulmonary infiltrates'	Jerrica Sullivan (b) (4)	09 Apr 2021 20:39:08
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08



US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '08 Jan 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:39:08

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US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '13 Jan 2021'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:39:08

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US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
	(b) (4), (b) (6)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jerrica Sullivan (b) (4)	09 Apr 2021 20:39:08
	(b) (4)	



US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'No (N)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08



US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'None (NONE)'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '1'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08



US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered '0'	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:47
User entered empty.	(b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:39:08

US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 20:39:08

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US3232157

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 20:39:08

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US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 20:55:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 20:55:09
Data point term sent to Coder	System	27 Apr 2021 20:01:17
User entered 'nausea'	Jerrica Sullivan (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43



US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Mar 2021'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Apr 2021'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43



US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:00:43

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US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43



US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:09:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:09:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:09:41
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:00:43
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:09:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:09:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:09:41
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:00:43
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43



US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:00:43

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 20:00:43

---

US3232157

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 20:00:43

---



US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 20:55:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 20:55:57
Data point term sent to Coder	System	27 Apr 2021 20:02:50
User entered 'vomiting'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Mar 2021'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:01:42

---

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42



US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Apr 2021'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:01:42

---

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42



US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:10:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:10:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:10:23
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:01:42
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42



US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:10:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:10:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:10:23
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:01:42
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:01:42



US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 20:01:42

---

US3232157

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 20:01:42

---

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Cachexia, LLT: Cachexia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 20:55:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 20:55:57
Data point term sent to Coder	System	27 Apr 2021 20:02:43
User entered 'cachexia'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Mar 2021'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39



US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:02:39

---

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39



US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39



US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:11:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:11:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:11:19
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:02:39
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:11:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:11:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:11:19
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:02:39
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39



US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:02:39

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 20:02:39

---

US3232157

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 20:02:39

---

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 20:57:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 20:57:50
Data point term sent to Coder	System	27 Apr 2021 20:03:53
User entered 'weakness'	Jerrica Sullivan (b) (4)	27 Apr 2021 20:03:24
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24



US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Mar 2021'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:03:24

---

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:03:24

---

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24



US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24



US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:12:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:12:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:12:00
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:03:24
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:12:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:12:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:12:00
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:03:24
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24



US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:03:24

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 20:03:24

---

US3232157

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 20:03:24

---

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 20:57:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 20:57:50
Data point term sent to Coder	System	27 Apr 2021 20:04:54
User entered 'fatigue'	Jerrica Sullivan (b) (4)	27 Apr 2021 20:04:20
	(b) (4)	

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20



US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Mar 2021'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:04:20

---

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20



US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 20:04:20

---

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20



US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:12:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:12:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:12:44
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:04:20
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:12:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:12:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:12:44
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:04:20
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20



US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

None

Audit	User	Time (GMT)
User entered '1'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jerrica Sullivan (b) (4) (b) (4)	27 Apr 2021 20:04:20

US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 20:04:20

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US3232157

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:11:01

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 20:04:20

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:11:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:01
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:06:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
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.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 21:00:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:00:32
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	04 Nov 2020 21:00:17 04 Nov 2020 20:59:47
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 22:09:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 22:09:45
Data point term sent to Coder User entered 'aspirin'	System Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33 09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Per DM CLR: Please update CM indication to include the underlying medical condition that this medication is being given to prevent (i.e.: Cardiovascular prophylaxis, Thrombosis prophylaxis etc.). Please update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM). Query 'Per DM CLR: Please update CM indication to include the underlying medical condition that this medication is being given to prevent (i.e.: Cardiovascular prophylaxis, Thrombosis prophylaxis etc.). Please update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 15:03:50
Query 'Per DM CLR: Please update CM indication to include the underlying medical condition that this medication is being given to prevent (i.e.: Cardiovascular prophylaxis, Thrombosis prophylaxis etc.). Please update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 20:59:51
User entered 'cardiac PROPHYLACTIC' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 20:59:47
User opened query 'Per DM CLR: Please update CM indication to include the underlying medical condition that this medication is being given to prevent (i.e.: Cardiovascular prophylaxis, Thrombosis prophylaxis etc.). Please update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM). User entered 'prophylactic'	(b) (4), (b) (6) (b) (4), (b) (6)  Adreanna Pou (b) (4) (b) (4)	28 Oct 2020 20:12:26  09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '81'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'un UNK 2000'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:07:44



US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:07:44

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:07:44

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 22:07:44

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
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.	(b) (4) Coder Import (b) (4) (b) (4)	04 Nov 2020 21:03:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:03:29
Data point term sent to Coder	System	04 Nov 2020 21:02:23
Data point term sent to Coder	System	04 Nov 2020 21:01:20
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:00:44
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)	09 Sep 2020 22:09:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 22:09:46
Data point term sent to Coder	System	09 Sep 2020 22:08:33
User entered 'atorvastatin'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Per DM CLR: Please update CM indication to include the specific medical diagnosis associated with CHOLESTEROL (i.e.: high cholesterol, hyperlipidemia etc.). Please update CM indication and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 15:04:04
User entered 'HYPERLIPIDEMIA' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:01:24
Query 'Per DM CLR: Please update CM indication to include the specific medical diagnosis associated with CHOLESTEROL (i.e.: high cholesterol, hyperlipidemia etc.). Please update CM indication and ensure to reconcile with the MH page so there is a match as appropriate. ' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:00:48
User entered 'hyperlipidemia CHOLESTEROL' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:00:44
User opened query 'Per DM CLR: Please update CM indication to include the specific medical diagnosis associated with CHOLESTEROL (i.e.: high cholesterol, hyperlipidemia etc.). Please update CM indication and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 20:12:56
User entered 'cholesterol'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '40'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'un UNK 2000'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:08:33

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:08:33

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:08:33

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 22:08:33

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Sep 2020 22:12:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 22:12:48
Data point term sent to Coder	System	09 Sep 2020 22:11:37
User entered 'pantoprazole'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'gerd'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '40'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'un UNK 2018'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:11:20

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:11:20

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:11:20

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 22:11:20

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 22:13:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 22:13:42
Data point term sent to Coder	System	09 Sep 2020 22:12:38
User entered 'famotidine'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'reflux'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '20'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'un UNK 2018'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:12:28

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:12:28

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:12:28

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 22:12:28

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 09:38:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 09:38:32
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	04 Nov 2020 21:08:33 04 Nov 2020 21:08:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 06:12:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 06:12:54
Data point term sent to Coder User entered 'valocyclovir'	System Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:39 09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add this medical condition and all applicable details to the Med History eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Dec 2020 15:05:45
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add this medical condition and all applicable details to the Med History eCRF as appropriate.' answered with 'corrected' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:08:29
User entered 'herpes simplex virus 2 (face)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	04 Nov 2020 21:08:26
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 this medical condition and all applicable details to the Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 20:13:45
User entered 'cold sores'	Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '500'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'as needed (PRN)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '05 Apr 2019' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	04 Nov 2020 21:09:26
User entered 'un UNK 2019'	(b) (4) Adreanna Pou (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Adreanna Pou (b) (4) (b) (4)	09 Sep 2020 22:13:36



US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 22:13:36

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 22:13:36

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 22:13:36

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Jan 2021 18:25:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Jan 2021 18:25:05
Data point term sent to Coder	System	12 Jan 2021 18:09:35
User entered 'ZINC'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'COVID-19'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '100'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:09:28



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
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).	(b) (4), (b) (6)	03 Mar 2021 15:17:48
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).	Jerrica Sullivan (b) (4)	02 Mar 2021 16:43:49
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Mar 2021 16:42:21
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)	02 Mar 2021 03:54:09
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:09:28



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '22 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Mar 2021 16:42:21
User entered empty.	Jerrica Sullivan (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:00
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:00
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:00
User entered '804 (804)'	(b) (4), (b) (6) System	12 Jan 2021 18:09:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:11:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:11:56
Data point term sent to Coder	System	12 Jan 2021 18:10:35
User entered 'AZITHROMYCIN'	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'COVID-19'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '500'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:10:02



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:04
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:04
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:04
User entered '804 (804)'	(b) (4), (b) (6) System	12 Jan 2021 18:10:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	Coder Import	12 Jan 2021 19:25:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import	12 Jan 2021 19:25:58
Data point term sent to Coder	System	12 Jan 2021 18:10:36
User entered 'AZITHROMYCINN'	Jerrica Sullivan	12 Jan 2021 18:10:27



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'COVID-19'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '250'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	Jerrica Sullivan (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:10:27



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	Jerrica Sullivan	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:10:27

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:10:27



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:09
User entered '804 (804)'	(b) (4), (b) (6) System	12 Jan 2021 18:10:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:13:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:13:01
Data point term sent to Coder	System	12 Jan 2021 18:11:36
User entered 'VITAMIN D3'	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'COVID-19'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '200'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 13:04:50
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	11 Mar 2021 14:55:13
User entered 'IU (IU)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	11 Mar 2021 14:55:06
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:20:16
User entered 'mg (mg)'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
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).	(b) (4), (b) (6)	03 Mar 2021 15:19:42
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).	Jerrica Sullivan (b) (4)	02 Mar 2021 16:47:30
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Mar 2021 16:47:26
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)	02 Mar 2021 03:54:25
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '22 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Mar 2021 16:47:26
User entered empty.	Jerrica Sullivan (b) (4)	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:19



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:16
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:16
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:16
User entered '804 (804)'	(b) (4), (b) (6) System	12 Jan 2021 18:11:19

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:13:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:13:56
Data point term sent to Coder	System	12 Jan 2021 18:12:37
User entered 'VITAMIN C'	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'COVID-19'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '1000'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
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).	(b) (4), (b) (6)	03 Mar 2021 15:20:06
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).	Jerrica Sullivan (b) (4)	02 Mar 2021 16:47:49
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Mar 2021 16:47:42
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)	02 Mar 2021 03:54:33
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:11:39



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '22 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Mar 2021 16:47:42
User entered empty.	Jerrica Sullivan (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:30
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:30
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:30
User entered '804 (804)'	(b) (4), (b) (6) System	12 Jan 2021 18:11:39

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Jan 2021 21:59:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 21:59:07
Data point term sent to Coder	System	12 Jan 2021 18:12:37
User entered 'MEALTONIN'	Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'COVID-19'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '5'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
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).	(b) (4), (b) (6)	03 Mar 2021 15:20:27
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).	Jerrica Sullivan (b) (4)	02 Mar 2021 16:50:34
User entered 'No (N)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Mar 2021 16:50:28
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)	02 Mar 2021 03:54:41
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '22 Jan 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	02 Mar 2021 16:50:28
User entered empty.	Jerrica Sullivan (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:16:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:59
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:12:02

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:59
User entered '1'	(b) (4), (b) (6) System	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:16:59
User entered '804 (804)'	(b) (4), (b) (6) System	12 Jan 2021 18:12:02

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: TONICS, ATC: TONICS, PRODUCT: DIETARY SUPPLEMENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:45:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:45:54
Data point term sent to Coder	System	03 Mar 2021 18:03:23
Data point term sent to Coder	System	18 Feb 2021 17:34:20
User entered 'IB Guard'	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 10:51:04
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	03 Mar 2021 18:03:03
User entered 'GASTROENTERITIS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	03 Mar 2021 18:02:34
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 00:26:57
User entered 'Irritable bowel'	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '2'	Jerrica Sullivan (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'capsule (CAPSULE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '15 Feb 2021'	Jerrica Sullivan (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	Jerrica Sullivan (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	Jerrica Sullivan (b) (4)	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:43
User entered '1'	(b) (4), (b) (6) System	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:43
User entered '1'	(b) (4), (b) (6) System	18 Feb 2021 17:34:07



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:59:43
User entered '804 (804)'	(b) (4), (b) (6) System	18 Feb 2021 17:34:07

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE, PRODUCTSYNONYM: GAS X - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	03 Mar 2021 18:04:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 18:04:45
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	03 Mar 2021 18:03:23 03 Mar 2021 18:02:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE, PRODUCTSYNONYM: GAS X - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	18 Feb 2021 17:36:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 17:36:53
Data point term sent to Coder	System	18 Feb 2021 17:35:25
User entered 'gas x'	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 10:52:39
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated indication ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	03 Mar 2021 18:02:56
User entered 'GASTROENTERITIS' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	03 Mar 2021 18:02:49
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 00:27:49
User entered 'irritable bowel'	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 125 MG, 180 MG, 250 MG, etc.) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	26 Mar 2021 09:52:00
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 125 MG, 180 MG, 250 MG, etc.) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'per monitor, this is acceptable dose unit ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	22 Mar 2021 13:38:40
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 125 MG, 180 MG, 250 MG, etc.) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Mar 2021 09:10:26
User entered '2'	Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'capsule (CAPSULE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '15 Feb 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	18 Feb 2021 17:34:28



US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 17:34:28

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 17:34:28

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Feb 2021 17:34:28

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:28
Data point term sent to Coder	System	25 Mar 2021 15:47:29
User entered 'flagyl'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'sepsis/cholangitis'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '500'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'three times daily (TID)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '13 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '23 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:00:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:00:16
User entered '3'	(b) (4), (b) (6) System	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:00:16
User entered '1'	(b) (4), (b) (6) System	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:00:16
User entered '804 (804)'	(b) (4), (b) (6) System	25 Mar 2021 15:47:14

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	08 Apr 2021 14:58:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:58:50
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	08 Apr 2021 13:32:06 08 Apr 2021 13:31:38
User signature succeeded.	(b) (4) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 15:49:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 15:49:42
Data point term sent to Coder User entered 'zofran'	System Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:30 25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 17:23:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:31:53
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:31:38
User entered 'NAUSEA secondary to worsening gastroesophageal reflux disease' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:31:38
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if applicable. Else, clarify. '(Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 09:51:28
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User entered 'nausea'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '4'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'as needed (PRN)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '13 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 15:47:41
	(b) (4)	

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:47:41

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:47:41

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:47:41

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:47:41

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:11:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:11:50
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	08 Apr 2021 13:33:07 08 Apr 2021 13:32:46
User signature succeeded.	(b) (4) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 16:05:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:05:28
Data point term sent to Coder User entered 'phenergan'	System Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:30 25 Mar 2021 15:48:05



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
Signature has been broken.	(b) (4) Jerrica Sullivan (b) (4)	08 Apr 2021 13:32:46
User entered 'NAUSEA secondary to worsening gastroesophageal reflux disease' reason for change:	(b) (4) Jerrica Sullivan (b) (4)	08 Apr 2021 13:32:46
Data Entry Error		
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'nausea'	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 15:48:05
	(b) (4)	

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '25'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'as needed (PRN)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '13 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:48:05

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:48:05

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:48:05

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 15:48:05

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOID, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Mar 2021 06:09:56
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 Mar 2021 06:09:56
Data point term sent to Coder	System	25 Mar 2021 15:58:56
Data point term sent to Coder	System	25 Mar 2021 15:57:53
User entered 'budesonide'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User closed query 'Per DM CLR: Please note that there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 17:29:15
Query 'Per DM CLR: Please note that there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated ae log ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:37:30
User opened query 'Per DM CLR: Please note that there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 10:05:52
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User entered 'pulmonary infiltrates'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '90'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'ug (ug)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'twice daily (BID)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 15:58:30
User entered 'Oral (ORAL)'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Jan 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:57:28



US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 15:57:28

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:57:28

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 15:57:28

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\202003.	(b) (4), (b) (6) Coders Import (b) (4) (b) (4)	08 Apr 2021 15:02:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coders Import (b) (4) (b) (4)	08 Apr 2021 15:02:58
Data point term sent to Coder	System	08 Apr 2021 13:36:13
Coding entries removed.	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:35:23
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\202003.	Coders Import (b) (4) (b) (4)	30 Mar 2021 00:44:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coders Import (b) (4) (b) (4)	30 Mar 2021 00:44:20
Data point term sent to Coder	System	25 Mar 2021 15:58:54
User entered 'dicyclomine'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User closed query 'Per CDM: Please verify if this pertains to ( #11) CHOLANGITIS (start date 12-MAR-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' (Site from DM). Query 'Per CDM: Please verify if this pertains to ( #11) CHOLANGITIS (start date 12-MAR-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' answered with 'correct as entered, diagnosis confirmed after medication was started' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4)	15 Apr 2021 15:47:43 12 Apr 2021 17:52:48
User opened query 'Per CDM: Please verify if this pertains to ( #11) CHOLANGITIS (start date 12-MAR-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 17:32:47
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 17:32:47
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:35:43
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:35:23
User entered 'GASTRIC EMPTYING secondary to cholangitis' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:35:23

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 10:06:34
	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User entered 'gastric emptying'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '10'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'twice daily (BID)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '08 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 15:58:10

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 15:58:10

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:58:10

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 15:58:10

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	06 Apr 2021 07:35:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:35:53
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	05 Apr 2021 16:23:25 05 Apr 2021 16:22:42
User signature succeeded.	(b) (4) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:22
Data point term sent to Coder User entered 'fentanyl'	System Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:57 25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
Signature has been broken.	(b) (4) Jerrica Sullivan (b) (4)	05 Apr 2021 16:22:42
User entered 'ABDOMINAL PAIN (PANCREATIC MASS)' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4)	05 Apr 2021 16:22:42
User signature succeeded.	(b) (4) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'abdominal pain'	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 16:01:55
	(b) (4)	

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '144'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'ug (ug)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'twice daily (BID)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Transdermal (TRANSDERMAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:01:55

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 16:01:55

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:01:55

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 16:01:55

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE, PRODUCTSYNONYM: REGLAN [METOCLOPRAMIDE] - version WHODrug-Global-B3\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:18:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:18:49
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4)	08 Apr 2021 13:37:14 08 Apr 2021 13:36:56
User signature succeeded.	(b) (4) Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE, PRODUCTSYNONYM: REGLAN [METOCLOPRAMIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:46:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:46:49
Data point term sent to Coder User entered 'reglan'	System Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:59 25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User closed query 'Per CDM: Please verify if this pertains to ( #11) CHOLANGITIS (start date 12-MAR-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' (Site from DM). Query 'Per CDM: Please verify if this pertains to ( #11) CHOLANGITIS (start date 12-MAR-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' answered with 'correct as entered, diagnosis confirmed after medication was started' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	15 Apr 2021 15:47:52
User opened query 'Per CDM: Please verify if this pertains to ( #11) CHOLANGITIS (start date 12-MAR-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' answered with 'correct as entered, diagnosis confirmed after medication was started' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	12 Apr 2021 17:53:30
User opened query 'Per CDM: Please verify if this pertains to ( #11) CHOLANGITIS (start date 12-MAR-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 17:35:54
Query 'Per CDM: Please verify if this pertains to ( #11) CHOLANGITIS (start date 13-MAR-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 17:35:34
User opened query 'Per CDM: Please verify if this pertains to ( #11) CHOLANGITIS (start date 13-MAR-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 17:35:23
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 17:35:23

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM). Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:37:31
	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:36:56
User entered 'GASTRIC EMPYTING secondary to cholangitis' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:36:56
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 10:06:54
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User entered 'gastric emptying'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '10'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 16:02:32
	(b) (4)	

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'twice daily (BID)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '11 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:02:32

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 16:02:32
	(b) (4)	



US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 16:02:32

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:02:32

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 16:02:32

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 11:47:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:47:56
Data point term sent to Coder	System	25 Mar 2021 16:07:09
User entered 'remeron (mirtazapine)'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'insomnia'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '15'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 16:06:50
	(b) (4)	

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (12MAR2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (12MAR2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'updated' (Site from DM). User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (12MAR2021). Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) Jerrica Sullivan (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) Rambod Rouhbakhsh (b) (4)	12 Apr 2021 17:33:59 08 Apr 2021 13:40:57 07 Apr 2021 10:08:33 02 Apr 2021 14:15:57
User entered '11 Mar 2021'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 16:06:50
	(b) (4)	



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:06:50

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4)	25 Mar 2021 16:06:50
	(b) (4)	

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:06:50

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:06:50

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 16:06:50

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: ULTRAM [TRAMADOL HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 12:26:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 12:26:28
Data point term sent to Coder	System	25 Mar 2021 16:09:14
User entered 'ultram'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	Jerrica Sullivan	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'abdominal pain'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:08:43



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '50'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'as needed (PRN)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
Signature has been broken.	Jerrica Sullivan (b) (4)	05 Apr 2021 16:25:14
User entered '11 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	05 Apr 2021 16:25:14
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Mar 2021 16:30:04
User entered 'un Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Mar 2021 16:30:04
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Mar 2021 16:08:43
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 16:08:43



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
Signature has been broken.	Jerrica Sullivan (b) (4)	05 Apr 2021 16:25:14
User entered '11 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	05 Apr 2021 16:25:14
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	25 Mar 2021 16:30:04
User entered 'un Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	25 Mar 2021 16:30:04
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	25 Mar 2021 16:08:43
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:18:59
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:08:43

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:48:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:48:30
Data point term sent to Coder	System	25 Mar 2021 16:32:45
User entered 'tylenol'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'fever'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '1000'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once (ONCE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:04
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:32:20

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:04
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:32:20



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:04
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:32:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 17:01:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 17:01:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 05:36:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 05:36:32
Data point term sent to Coder Coding entries removed.	System	08 Apr 2021 13:43:22
User signature succeeded.	Jerrica Sullivan (b) (4)	08 Apr 2021 13:42:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\202003.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Mar 2021 10:36:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Mar 2021 10:36:42

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data point term sent to Coder	System	25 Mar 2021 16:35:50
User entered 'normal saline (sodium chloride)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:35:00
	(b) (4)	

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	15 Apr 2021 15:51:49
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:42:42
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:42:32
User entered 'FLUID RESUSCITATION secondary to dehydration' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:42:32
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 10:10:44
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User entered 'fluid resuscitation'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '1000'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mL (mL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:35:00



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 09:38:56
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered with 'TV ran overnight' (Site from System).	Jerrica Sullivan (b) (4)	05 Apr 2021 16:28:40
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	05 Apr 2021 16:28:25
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User entered 'once (ONCE)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
Signature has been broken.	Jerrica Sullivan (b) (4)	05 Apr 2021 16:28:25
User entered '13 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	05 Apr 2021 16:28:25
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:35:00



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:12
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:12
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:12
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:35:00

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:12:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:12:42
Data point term sent to Coder	System	25 Mar 2021 16:37:51
User entered 'piperacillin-tazobactam'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'cholangitis/sepsis'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '3.375'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'g (g)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'three times daily (TID)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '13 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:20
User entered '3'	(b) (4), (b) (6) System	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:20
User entered '1'	(b) (4), (b) (6) System	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:20
User entered '804 (804)'	(b) (4), (b) (6) System	25 Mar 2021 16:36:57

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 05:27:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 05:27:28
Data point term sent to Coder Coding entries removed.	System	08 Apr 2021 13:40:16
User signature succeeded.	Jerrica Sullivan (b) (4)	08 Apr 2021 13:39:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Mar 2021 13:26:23
Data point term sent to Coder User entered 'lovenox'	Coder Import (b) (4)	31 Mar 2021 13:26:23
	System	25 Mar 2021 16:37:51
	Jerrica Sullivan (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:37:46



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for XXX). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 17:24:23
Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for XXX). Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	08 Apr 2021 13:39:36
Signature has been broken.	Jerrica Sullivan (b) (4)	08 Apr 2021 13:39:20
User entered 'PROPHYLACTIC cardiac' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Apr 2021 13:39:20
User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for XXX). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:11:09
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'prophylactic'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '40'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 17:25:29
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Jerrica Sullivan (b) (4)	08 Apr 2021 13:40:00
Signature has been broken.	Jerrica Sullivan (b) (4)	08 Apr 2021 13:39:20
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	08 Apr 2021 13:39:20
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:11:19
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Intramuscular (INTRAMUSCULAR)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '13 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:25
User entered '1'	(b) (4), (b) (6) System	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:25
User entered '1'	(b) (4), (b) (6) System	25 Mar 2021 16:37:46

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:25
User entered '804 (804)'	(b) (4), (b) (6) System	25 Mar 2021 16:37:46



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:39:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:39:28
Data point term sent to Coder	System	25 Mar 2021 16:38:52
User entered 'morphine'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'abdominal pain'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '2'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'as needed (PRN)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '13 Mar 2021'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:32
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:38:26



US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:32
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:32
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:38:26

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 15:12:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 15:12:53
Data point term sent to Coder Coding entries removed.	System	08 Apr 2021 13:34:10
User signature succeeded.	Jerrica Sullivan (b) (4)	08 Apr 2021 13:33:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 16:40:28
Data point term sent to Coder User entered 'phenergan'	Coder Import (b) (4)	25 Mar 2021 16:40:28
	System	25 Mar 2021 16:39:54
	Jerrica Sullivan (b) (4)	25 Mar 2021 16:39:27
	(b) (4)	

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
Signature has been broken.	(b) (4) Jerrica Sullivan (b) (4)	08 Apr 2021 13:33:47
User entered 'NAUSEA secondary to worsening gastroesophageal reflux disease' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:33:47
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'nausea'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12.5'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'as needed (PRN)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '13 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:36
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:36
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:39:27

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:36
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:36
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:39:27

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE HYDROCHLORIDE, PRODUCTSYNONYM: XYLOCAINE-MPF - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:51:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:51:46
Data point term sent to Coder	System	05 Apr 2021 16:27:32
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
Data point term sent to Coder	System	25 Mar 2021 16:40:55
User entered 'xylocaine-mpf 2%'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 17:49:31
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'this is listed on con procedures list and corresponds with aes marked con procedure ' (Site from DM).	Jerrica Sullivan (b) (4) (b) (4)	07 Apr 2021 12:44:57
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 or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 10:11:42
Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:26:34
User entered 'PRE-OP egd' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:26:34
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'pre-op'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '80'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:20



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once (ONCE)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:20



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:17:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:17:50
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:40:20

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:17:50
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:17:50
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:40:20

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:06:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:06:41
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4) (b) (4)	16 Apr 2021 14:06:03 16 Apr 2021 14:05:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 13:42:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 13:42:47
Data point term sent to Coder Coding entries removed.	System Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:42:22 08 Apr 2021 13:42:06
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL, PRODUCTSYNONYM: DIPRIVAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:41:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 16:41:28
Data point term sent to Coder User entered 'diprivan'	System Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:55 25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:54



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User closed query 'Per CDM RQ: Response noted, however ANESTHESIA EGD is not an underlying condition. Please consider to update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 10:59:56
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
Query 'Per CDM RQ: Response noted, however ANESTHESIA EGD is not an underlying condition. Please consider to update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM).	(b) (4)	16 Apr 2021 14:05:46
User entered 'ANESTHESIA EGD secondary to abdominal pain' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	16 Apr 2021 14:05:10
User opened query 'Per CDM RQ: Response noted, however ANESTHESIA EGD is not an underlying condition. Please consider to update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:37:40
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, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:37:40

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM). Signature has been broken.	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:42:11
	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:42:06
User entered 'ANESTHESIA EGD' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 13:42:06
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, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	07 Apr 2021 10:12:05
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User entered 'anesthesia'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '50'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once (ONCE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Intravenous (INTRAVENOUS)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:54



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12 Mar 2021'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	Jerrica Sullivan (b) (4)	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:40:54



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:50
User entered empty.	(b) (4), (b) (6) System	25 Mar 2021 16:40:54

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	02 Apr 2021 14:15:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 14:01:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 14:01:28
Data point term sent to Coder	System	25 Mar 2021 17:20:48
User entered 'levaquin'	Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'cholangitis/sepsis'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '500'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'once daily (QD)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	Jerrica Sullivan (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'Oral (ORAL)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '13 Mar 2021'	Jerrica Sullivan (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '23 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:19:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	25 Mar 2021 17:20:33



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:57
User entered '1'	(b) (4), (b) (6) System	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:57
User entered '1'	(b) (4), (b) (6) System	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:19:57
User entered '804 (804)'	(b) (4), (b) (6) System	25 Mar 2021 17:20:33

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 20:35:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 20:35:45
Data point term sent to Coder	System	09 Apr 2021 20:34:33
User entered 'aleve'	Jerrica Sullivan (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'No (N)'	Jerrica Sullivan (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'abdominal pain'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered '220'	Jerrica Sullivan (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:33:24



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'twice daily (BID)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'Oral (ORAL)'	Jerrica Sullivan	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered '25 Feb 2021'	Jerrica Sullivan (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered '0'	Jerrica Sullivan (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'No (N)'	Jerrica Sullivan (b) (4)	09 Apr 2021 20:33:24



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Apr 2021 20:33:40
User entered '10 Mar 2021' reason for change: Data Entry Error	Jerrica Sullivan (b) (4)	09 Apr 2021 20:33:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Apr 2021 20:33:24
User entered '10 Mar 201' (non-conformant).	Jerrica Sullivan (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	01 May 2021 11:20:03
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
User entered '2'	(b) (4), (b) (6) System	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
User entered '1'	(b) (4), (b) (6) System	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:03
User entered '804 (804)'	(b) (4), (b) (6) System	09 Apr 2021 20:33:24

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: ANTIMETABOLITES, ATC: PYRIMIDINE ANALOGUES, PRODUCT: FLUOROURACIL, PRODUCTSYNONYM: 5 FU - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 12:13:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 12:13:53
Data point term sent to Coder User entered '5-FU'	System Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:37:36 09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'Metastatic pancreatic adenocarcinoma'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered '2400'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'mg (mg)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'other (OTHER)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'continuous infusion'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered '30 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36



US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered '0'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'Yes (Y)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered 'No (N)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	09 Apr 2021 20:36:36

US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:11:01**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:36:36

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US3232157

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 16:11:01**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:36:36

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US3232157

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:01

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 20:36:36

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US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:11:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:23
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:23:32
Signature has been broken.	Rambod Rouhbakhsh	05 Apr 2021 16:19:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 16:19:51
User signature succeeded.	Jerrica Sullivan (b) (4)	02 Apr 2021 14:15:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	08 Mar 2021 20:43:46
User entered 'Yes (Y)'	Jerrica Sullivan (b) (4)	09 Sep 2020 22:13:43
	(b) (4)	



US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:01

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered '13 Mar 2021'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:20:25

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered 'Endoscopic Retrograde Cholangiopancreatography'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:20:25

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered 'Adverse Event (AE)'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:20:25

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:01

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered empty.	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:20:25

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:01

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered '12 Mar 2021'	Jerrica Sullivan (b) (4)	05 Apr 2021 16:27:21

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:49
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered 'Esophagogastroduodenoscopy'	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	05 Apr 2021 16:27:21

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 16:23:32
User entered 'Adverse Event (AE)'	Rambod Rouhbakhsh	05 Apr 2021 16:27:21
	(b) (4)	
	Jerrica Sullivan (b) (4)	
	(b) (4)	

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:01

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:49
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered empty.	Jerrica Sullivan (b) (4)	05 Apr 2021 16:27:21



US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:01

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered '25 Mar 2021'	Jerrica Sullivan (b) (4)	08 Apr 2021 17:18:48

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:01

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:53
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	23 Apr 2021 15:23:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:27:31
Signature has been broken.	(b) (4), (b) (6) Jerrica Sullivan (b) (4)	16 Apr 2021 19:23:29
User entered 'laparoscopic biopsy of peritoneal and omental masses with frozen section and INFUSAPORT PLACEMENT' reason for change: Data Entry Error	(b) (4) Jerrica Sullivan (b) (4) (b) (4)	16 Apr 2021 19:23:29
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	09 Apr 2021 16:23:32
User entered 'infusaport placement'	Jerrica Sullivan (b) (4) (b) (4)	08 Apr 2021 17:18:48

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered 'Adverse Event (AE)'	Jerrica Sullivan (b) (4)	08 Apr 2021 17:18:48

US3232157

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:01

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:51:53
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:27:31
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered empty.	Jerrica Sullivan (b) (4)	08 Apr 2021 17:18:48

US3232157

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:11:01

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 08:14:02
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 18:06:53
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	13 Apr 2021 13:54:47
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 13:54:07
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	13 Apr 2021 13:54:07
User entered '12 Apr 2021'	Jerrica Sullivan (b) (4) (b) (4)	13 Apr 2021 13:50:22

US3232157

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:11:01

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 08:14:02
User signature succeeded.	Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 18:06:55
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	Jerrica Sullivan (b) (4) (b) (4)	13 Apr 2021 13:54:51
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 13:54:07
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	13 Apr 2021 13:54:07
User entered 'Other (OTHER)'	Jerrica Sullivan (b) (4) (b) (4)	13 Apr 2021 13:50:22

US3232157

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:11:01

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 08:14:02
User signature succeeded.	Rambod Rouhbakhsh (b) (4)	16 Apr 2021 16:01:22
User entered empty; reason for change Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	13 Apr 2021 13:54:07
User entered 'SUBJECT REACHED OUT TO PI, HIS PHYSICIAN HAS ADVISED NOT TO RECEIVE SECOND DOSE OF VACCINE DUE TO RECENT DIAGNOSIS OF Metastatic PANCREATIC adenocarcinoma on 22Mar2021.' reason for change: Data Entry Error	Jerrica Sullivan (b) (4) (b) (4)	13 Apr 2021 13:51:15
User entered 'Subject reached out to PI, his physician Jerrica Sullivan has advised not to receive second dose of vaccine due to recent diagnosis of malignant pancreatic mass'	Jerrica Sullivan (b) (4) (b) (4)	13 Apr 2021 13:50:22

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'USA-US105-2021-MRNA-1273-P301000001'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'Rambod'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'Petal'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'MS'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered '39465'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:23
User entered 'US'	(b) (4), (b) (6) System	12 Jan 2021 21:41:08

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	02 Feb 2021 21:44:11
User entered '1'	System	12 Jan 2021 21:41:08

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US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'USA-US105-2021-MRNA-1273-P301000001'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'Rambod'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'Petal'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'MS'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered '39465'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:23
User entered 'US'	(b) (4), (b) (6) System	12 Jan 2021 21:41:08

**US3232157**

**Folder: SAE USA-US105-2021-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:01**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	02 Feb 2021 21:44:11
User entered '1'	System	12 Jan 2021 21:41:08

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '12/Jan/2021 16:41'	(b) (4) System	12 Jan 2021 21:41:08



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:01

**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)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:23
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 21:41:08

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'USA-US105-2021-MRNA-1273-P301000001'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'No (N)'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'Rambod'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'Petal'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered 'MS'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 21:40:59
User entered '39465'	(b) (4), (b) (6) System	12 Jan 2021 21:40:24

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:23
User entered 'US'	(b) (4), (b) (6) System	12 Jan 2021 21:41:08



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Feb 2021 21:44:11
User entered '1'	System	12 Jan 2021 21:41:08

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
User entered '02/Feb/2021 16:44'	(b) (4) System	02 Feb 2021 21:44:11

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:01

**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)	22 Apr 2021 16:26:11
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	02 Apr 2021 14:15:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:44:23
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 21:44:11

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'USA-US105-2021-MRNA-1273-P301000008'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rambod'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Petal'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MS'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered '39465'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:41:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 13:25:45
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered 'US'	(b) (4) System	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 20:44:41
User entered '4'	System	27 Apr 2021 18:52:59
User entered '3'	System	19 Apr 2021 15:29:02
User entered '2'	System	12 Apr 2021 13:25:58
User entered '1'	System	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'USA-US105-2021-MRNA-1273-P301000008'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rambod'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Petal'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MS'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered '39465'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:41:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 13:25:45
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered 'US'	(b) (4) System	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 20:44:41
User entered '4'	System	27 Apr 2021 18:52:59
User entered '3'	System	19 Apr 2021 15:29:02
User entered '2'	System	12 Apr 2021 13:25:58
User entered '1'	System	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered '08/Apr/2021 17:27'	(b) (4) System	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:01

**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)	22 Apr 2021 16:26:24
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 13:25:45
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered '1'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'USA-US105-2021-MRNA-1273-P301000008'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rambod'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Petal'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MS'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered '39465'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:41:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 13:25:45
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered 'US'	(b) (4) System	08 Apr 2021 21:27:34

**US3232157**

**Folder: SAE USA-US105-2021-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:11:01**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 20:44:41
User entered '4'	System	27 Apr 2021 18:52:59
User entered '3'	System	19 Apr 2021 15:29:02
User entered '2'	System	12 Apr 2021 13:25:58
User entered '1'	System	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered '12/Apr/2021 09:25'	(b) (4) System	12 Apr 2021 13:25:58

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:01

**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)	22 Apr 2021 16:26:24
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 15:28:39
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	16 Apr 2021 16:01:22
User entered '1'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 13:25:58

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'USA-US105-2021-MRNA-1273-P301000008'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rambod'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Petal'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MS'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered '39465'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:41:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 13:25:45
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered 'US'	(b) (4) System	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 20:44:41
User entered '4'	System	27 Apr 2021 18:52:59
User entered '3'	System	19 Apr 2021 15:29:02
User entered '2'	System	12 Apr 2021 13:25:58
User entered '1'	System	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:11:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:23:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:26:24
User entered '19/Apr/2021 10:28'	(b) (4), (b) (6) System	19 Apr 2021 15:29:02



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:11:01

**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)
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 18:52:46
User signature succeeded.	Rambod Rouhbakhsh	23 Apr 2021 15:23:45
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 15:29:02

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'USA-US105-2021-MRNA-1273-P301000008'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'No (N)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rambod'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Rouhbakhsh'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MediSync Clinical Research Hattiesburg Clinic'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'Petal'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered 'MS'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
User signature succeeded.	(b) (4), (b) (6) Rambod Rouhbakhsh	09 Apr 2021 16:23:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:27:18
User entered '39465'	(b) (4), (b) (6) System	08 Apr 2021 21:27:01

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 20:41:05
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:26:24
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 13:25:45
User signature succeeded.	Rambod Rouhbakhsh	09 Apr 2021 16:23:32
User entered 'US'	(b) (4) System	08 Apr 2021 21:27:34



US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	27 Apr 2021 20:44:41
User entered '4'	System	27 Apr 2021 18:52:59
User entered '3'	System	19 Apr 2021 15:29:02
User entered '2'	System	12 Apr 2021 13:25:58
User entered '1'	System	08 Apr 2021 21:27:34

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:11:01

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Rambod Rouhbakhsh	28 Apr 2021 17:43:22
User entered '27/Apr/2021 15:44'	(b) (4) System	27 Apr 2021 20:44:41

US3232157

Folder: SAE USA-US105-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:11:01

**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.	Rambod Rouhbakhsh	28 Apr 2021 17:43:22
User entered '1'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 20:44:41