

US3362166 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:11:40

All time stamps listed in this document are displayed in GMT

US3362166

Form: Participant Creation

Data signed: (b) (4) 24 Apr 2021 00:24:26

Generated On: 09 Jun 2021 17:11:40

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[Participant ID](#)

US3362166

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

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US3362166

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Date of Informed Consent ( <i>dd MMM yyyy</i> )	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:20:23

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Condition	BILATERAL PULMONARY EMOBOLUS
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Condition	DIABETES TYPE II
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Condition	OBESITY
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) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1967
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 1967
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1967
Start Year (derived)	1967
Stop Month and Year (derived)	JAN 1967
Stop Year (derived)	1967

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	08:09 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 08:09
Height (xxx.x)	174.0 cm
Weight (xxx.x)	148.7 kg
BMI (xxx.x)	49.11481 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 00:20:23

Generated On: 09 Jun 2021 17:11:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:20:23

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

CONSTRUCTION WORKER

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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) 10 Apr 2021 00:20:23

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 186581

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) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Height	ND - Not Done
Weight	ND - Not Done



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	08:09 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 08:09
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:50
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 09:15 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

08:38 (24 HR)

Collection date and time (derived)

17 AUG 2020 08:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:37	17 AUG 2020 08:37
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

17 AUG 2020 09:47

PC Open Date & Time

17 AUG 2020 09:35

PC Close Date & Time

17 AUG 2020 12:05



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**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	17 AUG 2020 13:14
PC Open Date & Time	17 AUG 2020 13:00
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 19:27

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 20:18

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

---

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

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PC Time Stamp

21 AUG 2020 07:48

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PC Open Date & Time

20 AUG 2020 12:00

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PC Close Date & Time

21 AUG 2020 11:59

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US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 09:07

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 01:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**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

97.5 °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

23 AUG 2020 22:15

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**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

17 AUG 2020 09:48

PC Open Date & Time

17 AUG 2020 09:35

PC Close Date & Time

17 AUG 2020 12:05



US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**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

17 AUG 2020 13:14

PC Open Date & Time

17 AUG 2020 13:00

PC Close Date & Time

18 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 19:28

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 20:18

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 07:48

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 09:07

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 01:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 22:16

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**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 ☐



US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 09:48
PC Open Date & Time	17 AUG 2020 09:35
PC Close Date & Time	17 AUG 2020 12:05

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**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 ☐

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 13:15
PC Open Date & Time	17 AUG 2020 13:00
PC Close Date & Time	18 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**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 ☒

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 19:29
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:18
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**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 ☒



US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 07:48
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

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 ☒

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 09:07
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2721

EAB) (1725)

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 01:03
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**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 ☒

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 22:16
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3362166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3362166

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:04:59

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362166

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:04:59

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362166

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:04:59

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

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

Visit date (dd MMM yyyy)	14 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

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)	14 SEP 2020
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 08:10
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

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)	14 SEP 2020
Time of assessment (00:00-23:59)	09:48 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 09:48
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG



US3362166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3362166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 09:10 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 09:10

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

US3362166

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

08:24 (24 HR)

Collection date and time (derived)

14 SEP 2020 08:24

US3362166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:21	14 SEP 2020 08:21
Nasopharyngeal Swab 2	No		

US3362166

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 09:43

PC Open Date & Time

14 SEP 2020 09:30

PC Close Date & Time

14 SEP 2020 12:00

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**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 98.3 °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	14 SEP 2020 19:56
PC Open Date & Time	14 SEP 2020 12:55
PC Close Date & Time	15 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 18:49

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 17:22

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 21:19

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 00:42

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:22

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 15:45

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**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

14 SEP 2020 09:45

PC Open Date & Time

14 SEP 2020 09:30

PC Close Date & Time

14 SEP 2020 12:00

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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

14

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

14 SEP 2020 19:59

PC Open Date & Time

14 SEP 2020 12:55

PC Close Date & Time

15 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 18:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 17:22

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 21:19

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 00:42

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 12:22

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 15:45

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**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 ☐

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 09:46
PC Open Date & Time	14 SEP 2020 09:30
PC Close Date & Time	14 SEP 2020 12:00

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**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 ☐



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 20:00
PC Open Date & Time	14 SEP 2020 12:55
PC Close Date & Time	15 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**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 ☒

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 18:50
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 17:22
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**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 ☒

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:20
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 00:43
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

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 ☒

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:22
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**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 ☒

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 15:46
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3362166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362166

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3362166

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362166

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3362166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	07:40 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 07:40
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362166

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3362166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

08:02 (24 HR)

Collection date and time (derived)

12 OCT 2020 08:02

US3362166

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 16:05:04

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 14:15:26

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 17:55:59
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	14 NOV 2020 09:55:13
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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	19 NOV 2020 18:57:36
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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 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	25 NOV 2020 00:04:05
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

Date and time of submission

02 DEC 2020 15:09:25

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59



US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 00:48:26

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 00:02:33

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 00:26:53

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 01:16:02

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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

06 JAN 2021 01:07:48

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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

13 JAN 2021 00:13:28

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

<b>TIMEPOINT</b>	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 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	20 JAN 2021 00:02:35
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 00:15:35

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59



US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 03:33:21

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 06:45:42

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 02:51:45

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 01:05:16

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 04:36:33

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 03:08:31
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 05:20:00

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 00:36:49

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59



US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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

04 APR 2021 02:21:57

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 00:43:21

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 01:34:50

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 16:38:59

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

Date and time of submission

28 APR 2021 01:37:48

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAY 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59
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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59
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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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27 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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20 FEB 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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[Patient Cloud Open Date & Time](#)

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23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 FEB 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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06 MAR 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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13 MAR 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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20 MAR 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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27 MAR 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

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30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 APR 2022 00:01

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10 APR 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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13 APR 2022 00:01

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17 APR 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

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01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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12 JUN 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

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26 JUN 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

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10 JUL 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

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17 JUL 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

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24 JUL 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

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31 JUL 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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°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 ☐



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

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07 AUG 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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17 AUG 2022 00:01

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21 AUG 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

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28 AUG 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

Date and time of submission

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04 SEP 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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07 SEP 2022 00:01

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11 SEP 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**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 ☐

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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14 SEP 2022 00:01

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18 SEP 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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



**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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Date and time of submission

---

[Patient Cloud Open Date & Time](#)

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05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

09 OCT 2022 23:59

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US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

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

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3362166

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362166**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

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

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

US3362166

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:11:40

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 19:25:09



US3362166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:22:56

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362166

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:22:56

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362166

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362166

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362166

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3362166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

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) \_\_\_\_\_

US3362166

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

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.*

US3362166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

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

Collection date (dd MMM yyyy)	1 MAR 2021
-------------------------------	------------

Collection time (00:00-23:59)	14:40 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	1 MAR 2021 14:40
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US3362166

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362166

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362166

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:24:48

Generated On: 09 Jun 2021 17:11:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3362166**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

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*



**US3362166**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Apr 2021 00:24:26

Generated On: 09 Jun 2021 17:11:40

Date of Contact	1 DEC 2020
Time of Contact	11:05
Date and Time of Contact (derived)	1 DEC 2020 11:05
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

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"/>

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 NOV 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

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 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 NOV 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	37.0 C	
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 type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>



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Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

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 01 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 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 type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input 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 (5)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	3 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.9 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 type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 (7)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	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	04 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 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 01 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

	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"/>

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Apr 2021 00:24:26

Generated On: 09 Jun 2021 17:11:40

Date of Visit	1 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	1 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Apr 2021 00:24:26

Generated On: 09 Jun 2021 17:11:40

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

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

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	11:11 (24 HR)
Vital Signs Date and Time (derived)	1 DEC 2020 11:11
Height ( <i>xxx.x</i> )	174 cm
Weight ( <i>xxx.x</i> )	148.7 kg
Temperature ( <i>xxx.x</i> )	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	63 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 DEC 2020

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

US3362166

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 24 Apr 2021 00:24:27

Generated On: 09 Jun 2021 17:11:40

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

1 DEC 2020

US3362166

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

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

Visit date (dd MMM yyyy)	8 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

Date of updated informed consent (dd MMM yyyy) 8 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 8 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

07:35 (24 HR)

Collection date and time (derived)

8 JAN 2021 07:35



US3362166

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00 - 23:59)

07:36

Collection Date and Time (derived)

8 JAN 2021 07:36

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:16:05

Generated On: 09 Jun 2021 17:11:40

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3362166

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

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

US3362166

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

AEID

Adverse event

CRACKED TOOTH

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

30 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

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



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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

AEID

Adverse event

WORSENING HYPERTENSION

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)

14 SEP 2020

Start time (00:00-23:59)

00:00 (24 HR)

AE start date and time (derived)

14 SEP 2020 00:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

7 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

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 (4)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

AEID

Adverse event

UPPER RESPIRATORY ILLNESS

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)

28 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

7 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

AEID	USA-US112-2020-MRNA-1273-P30 1000015
Adverse event	WORSENING OF DIABETES TYPE 2
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)	24 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	7 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	25 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <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	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

---

ON 24 NOV 2020, THE SUBJECT  
USED A CO-WORKER'S  
GLUCOMETER TO CHECK HIS  
GLUCOSE. HIS BLOOD  
GLUCOSE LEVEL AT THAT  
TIME READ AS "HIGH".  
SUBJECT HAD REPORTEDLY  
STOPPED TAKING HIS INSULIN  
APPROXIMATELY 6 MONTHS  
PRIOR AFTER LOSING 50 LBS.  
SUBJECT WAS ADMITTED  
OVERNIGHT AFTER GLUCOSE  
ON CHEMISTRY WAS NOTED  
TO BE 704. NO ANION GAP OR  
ACIDOSIS. HE DID HAVE ACUTE  
KIDNEY INJURY. HE WAS  
PLACED IN OBSERVATION FOR  
IV FLUID RESUSCITATION AND  
INSULIN ADMINISTRATION.

---

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

---

US3362166

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

AEID	USA-US112-2020-MRNA-1273-P30 1000015
Adverse event	ACUTE KIDNEY INJURY
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)	24 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	25 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (8)

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

US3362166

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 27 Mar 2021 00:09:48

Generated On: 09 Jun 2021 17:11:40

---

ON 24 NOV 2020, THE SUBJECT  
USED A CO-WORKER'S  
GLUCOMETER TO CHECK HIS  
GLUCOSE. HIS BLOOD  
GLUCOSE LEVEL AT THAT  
TIME READ AS "HIGH".  
SUBJECT HAD REPORTEDLY  
STOPPED TAKING HIS INSULIN  
APPROXIMATELY 6 MONTHS  
PRIOR AFTER LOSING 50 LBS.  
SUBJECT WAS ADMITTED  
OVERNIGHT AFTER GLUCOSE  
ON CHEMISTRY WAS NOTED  
TO BE 704. NO ANION GAP OR  
ACIDOSIS. HE DID HAVE ACUTE  
KIDNEY INJURY. HE WAS  
PLACED IN OBSERVATION FOR  
IV FLUID RESUSCITATION AND  
INSULIN ADMINISTRATION.

---

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

---

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:54:10

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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.

---

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication XARELTO

Prophylaxis Yes ☐  
No ☒

Indication HISTORY OF PULMONARY  
EMBOLUS/ CARDIAC HEALTH  
AND WELLNESS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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 SEP 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication PRAVASTATIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication LANTUS

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

Dose per administration 40

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN MAY 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:54:09

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Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication TOOTH EXTRACTION/ TOOTH  
CRACKED

Dose per administration 10-325 MG

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication FRACTURED TOOTH  
RESULTING IN NEED FOR  
TOOTH EXTRACTION.

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)	1 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	8 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication VICTOZA

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE II

Dose per administration 0.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 1 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication VICTOZA

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS

Dose per administration 1.2

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)		01 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication LACTATED RINGERS BOLUS

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA/ACUTE  
KIDNEY INJURY

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication DEXTROSE (GLUTOSE) 40% GEL

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication DEXTROSE 50% IN WATER  
(D50W)

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication DEXTROSE 50% IN WATER  
(D50W)

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication GLUCAGON

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication HUMALOG (INSULIN LISPRO)

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

Dose per administration 10

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication INSULIN REGULAR (HUMULIN R)

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

Dose per administration 10

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication INSULIN REGULAR (HUMULIN R)

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

Dose per administration 10

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication LANTUS

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

Dose per administration 40

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

411 of 2721

EAB) (1725)



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication VICTOZA

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE II

Dose per administration 1.2

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

413 of 2721

EAB) (1725)

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)		
Start date completely unknown		True
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN MAY 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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

415 of 2721

EAB) (1725)

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 00:54:09

Generated On: 09 Jun 2021 17:11:40

	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)	7 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:54:10

Generated On: 09 Jun 2021 17:11:40

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 00:54:10

Generated On: 09 Jun 2021 17:11:40

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
01 OCT 2020	TOOTH EXTRACTION	Adverse Event	
01 OCT 2020	ROOT CANAL	Adverse Event	
24 NOV 2020	CHEMISTRY PANEL	Diagnostic	

US3362166

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:11:40

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



US3362166

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:11:40

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 ☐

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

SAEID	USA-US112-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

SAEID	USA-US112-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	11/DEC/2020 15:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

SAEID	USA-US112-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	16/DEC/2020 10:09
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

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

SAEID	USA-US112-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/DEC/2020 15:19
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

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

SAEID	USA-US112-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	20/JAN/2021 14:44
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

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

SAEID	USA-US112-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	21/JAN/2021 09:47
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

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

SAEID	USA-US112-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/FEB/2021 12:35
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



US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

SAEID	USA-US112-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:32
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

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Data signed: (b) (4) 24 Apr 2021 00:24:47

Generated On: 09 Jun 2021 17:11:40

SAEID	USA-US112-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	26/MAR/2021 14:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3362166 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

**US3362166**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:11:40**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:42:01
User entered 'US3362166'	RWS_ENDPOINT	17 Aug 2020 12:59:22
	ENDPOINT (b) (4)	

US3362166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 14:26:43

US3362166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4)	23 Sep 2020 18:45:24
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:59:23

US3362166

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

[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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Aug 2020 14:26:43

**US3362166**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'SCRN'	System	17 Aug 2020 14:26:43



**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered (b) (6) 1955'	RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 18:45:38
		17 Aug 2020 12:59:24

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered '65'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'YEARS'	System	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '65'	System	17 Aug 2020 14:27:38

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered 'Male (M)'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered 'l'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 14:27:14



**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:11:40**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:38
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 14:27:14

**US3362166**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:46
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 14:27:38



**US3362166**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'Aug 2020'	System	17 Aug 2020 14:27:38

**US3362166**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '2020'	System	17 Aug 2020 14:27:38

**US3362166**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:11:40**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:46
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	17 Aug 2020 14:27:38

US3362166

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 14:27:38

**US3362166**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:46
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:27:38

**US3362166**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:11:40**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:46
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:27:38

**US3362166**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:11:40**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:46
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 14:27:38

**US3362166**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:11:40**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4)	23 Sep 2020 18:45:46
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:59:23



**US3362166**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:11:40**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'I'	System	17 Aug 2020 14:27:43

**US3362166**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 14:27:43

US3362166

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:11:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:57
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:03:03

US3362166

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:11:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 04:27:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 04:27:43
Data point term sent to Coder	System	05 Sep 2020 19:04:30
User entered 'bilateral pulmonary embolus'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:08
	(b) (4)	

**US3362166**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'un UNK 2009'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:08

**US3362166**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:08

**US3362166**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:08

**US3362166**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'un UNK 2009'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:08



**US3362166**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:08

**US3362166**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'Jan 2009'	System	05 Sep 2020 19:04:08

**US3362166**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '2009'	System	05 Sep 2020 19:04:08

**US3362166**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'Jan 2009'	System	05 Sep 2020 19:04:08

**US3362166**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '2009'	System	05 Sep 2020 19:04:08

US3362166

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:11:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:46:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 19:06:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 19:06:37
Data point term sent to Coder	System	05 Sep 2020 19:05:31
User entered 'diabetes Type II'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 19:04:38

**US3362166**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'un UNK 2010'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:38

**US3362166**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:38



**US3362166**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:38

**US3362166**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:04:38

**US3362166**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:38

**US3362166**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'Jan 2010'	System	05 Sep 2020 19:04:38

**US3362166**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '2010'	System	05 Sep 2020 19:04:38

**US3362166**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered empty.	System	05 Sep 2020 19:04:38

**US3362166**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered empty.	System	05 Sep 2020 19:04:38

US3362166

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:11:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:06:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:06:36
Data point term sent to Coder	System	05 Sep 2020 19:05:32
User entered 'hypertension'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:59



**US3362166**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'un UNK 1990'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:59

**US3362166**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:59

**US3362166**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:59

**US3362166**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:04:59

**US3362166**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:04:59

**US3362166**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'Jan 1990'	System	05 Sep 2020 19:04:59

**US3362166**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '1990'	System	05 Sep 2020 19:04:59

**US3362166**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered empty.	System	05 Sep 2020 19:04:59



**US3362166**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered empty.	System	05 Sep 2020 19:04:59

US3362166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:06:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:06:36
Data point term sent to Coder	System	05 Sep 2020 19:05:31
User entered 'obesity'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:16

US3362166

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'un UNK 2000'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:16

**US3362166**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:16

**US3362166**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:16

**US3362166**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:05:16

**US3362166**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:16

**US3362166**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'Jan 2000'	System	05 Sep 2020 19:05:16



**US3362166**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '2000'	System	05 Sep 2020 19:05:16

**US3362166**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered empty.	System	05 Sep 2020 19:05:16

**US3362166**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered empty.	System	05 Sep 2020 19:05:16

US3362166

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:11:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:07:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:07:37
Data point term sent to Coder	System	05 Sep 2020 19:06:33
User entered 'hyperlipidemia'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:39

**US3362166**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'un UNK 2010'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:39

**US3362166**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:39

**US3362166**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:39

**US3362166**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:05:39



**US3362166**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:05:39

**US3362166**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'Jan 2010'	System	05 Sep 2020 19:05:39

**US3362166**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '2010'	System	05 Sep 2020 19:05:39

**US3362166**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered empty.	System	05 Sep 2020 19:05:39

**US3362166**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered empty.	System	05 Sep 2020 19:05:39

US3362166

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:11:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:07:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 19:07:37
Data point term sent to Coder	System	05 Sep 2020 19:06:33
User entered 'appendectomy'	Amy Thomassie (b) (4)	05 Sep 2020 19:06:17

**US3362166**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'un UNK 1967'	Amy Thomassie (b) (4)	05 Sep 2020 19:06:17

**US3362166**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:06:17



**US3362166**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:06:17

**US3362166**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered 'un UNK 1967'	Amy Thomassie (b) (4)	05 Sep 2020 19:06:17

**US3362166**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:46:56
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:06:17

**US3362166**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'Jan 1967'	System	05 Sep 2020 19:06:17

**US3362166**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '1967'	System	05 Sep 2020 19:06:17

**US3362166**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'Jan 1967'	System	05 Sep 2020 19:06:17

**US3362166**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '1967'	System	05 Sep 2020 19:06:17

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08



US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered '17 Aug 2020'	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
User closed query 'Per CDM: Please confirm if time 08:09 is AM or PM. Thank you!' (Site from DM).	(b) (4)	25 Sep 2020 07:52:28
Query 'Per CDM: Please confirm if time 08:09 is AM or PM. Thank you!' answered with 'am' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:42:50
User opened query 'Per CDM: Please confirm if time 08:09 is AM or PM. Thank you!' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:45:37
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered '08:09'	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08

**US3362166**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered '17 Aug 2020 08:09'	System	05 Sep 2020 19:08:08

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered '174.0' cm	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08
DataPoint set to visible.	System	17 Aug 2020 14:27:43

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered '148.7' kg	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08
DataPoint set to visible.	System	17 Aug 2020 14:27:43

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User closed query 'Per CDM: per sponsor review, BMI $\geq$ 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 07:10:55
Query 'Per CDM: per sponsor review, BMI $\geq$ 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:50:48
User opened query 'Per CDM: per sponsor review, BMI $\geq$ 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:37:45
User entered '49.11481'	System	05 Sep 2020 19:08:08
DataPoint set to visible.	System	17 Aug 2020 14:27:43

**US3362166**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'kg/m2'	System	05 Sep 2020 19:08:08
DataPoint set to visible.	System	17 Aug 2020 14:27:43

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:08
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:52:30
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:43:45
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:43:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:43:36
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:45:46
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered '36.9' C	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08



US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:59:08
DataPoint Un-verified.		24 Sep 2020 18:43:36
User entered empty; reason for change Data Entry Error		24 Sep 2020 18:43:36
DataPoint Verified.		23 Sep 2020 18:47:31
User entered 'Oral (Oral)'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 19:08:08

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 19:59:08
DataPoint Un-verified.		24 Sep 2020 18:43:36
User entered missing code ND - Not Done; reason fo change Data Entry Error		24 Sep 2020 18:43:36
DataPoint Verified.		23 Sep 2020 18:47:31
User entered '63'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 19:08:08

**US3362166**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'bpm'	System	05 Sep 2020 19:08:08

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4)	24 Mar 2021 19:59:08
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:43:36
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	24 Sep 2020 18:43:36
change Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered '16'	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08
	(b) (4)	

**US3362166**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'breaths/min'	System	05 Sep 2020 19:08:08

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4)	24 Mar 2021 19:59:08
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:43:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:43:36
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered '170'	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08
	(b) (4)	

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'mmHg'	System	05 Sep 2020 19:08:08



US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:08
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:43:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:43:36
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:47:31
User entered '79'	Amy Thomassie (b) (4)	05 Sep 2020 19:08:08

**US3362166**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User entered 'mmHg'	System	05 Sep 2020 19:08:08

**US3362166**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26

US3362166

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26

US3362166

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 18:48:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:48:39
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:08:27
	(b) (4)	

US3362166

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4)	23 Sep 2020 18:48:19
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 21:48:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:48:39
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 15:04:41
User entered '17 Aug 2020'	Amy Thomassie (b) (4)	05 Sep 2020 19:08:27

US3362166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

[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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

US3362166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

**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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

**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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

US3362166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

**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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

US3362166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

[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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

US3362166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

[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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

**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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

**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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

[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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

US3362166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

**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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34



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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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'construction worker'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

**US3362166**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:11:40**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

**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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

[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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34



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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 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered 'I'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

US3362166

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:11:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:34:26
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:20:24
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:25
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:09:34

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 19:55:57

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:56
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 19:55:57

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:48:56
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Aug 2020 19:55:57

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'VISIT1'	System	17 Aug 2020 19:55:57

US3362166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:21
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:35:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:02
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:49:44



US3362166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:21
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:35:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:56:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:56:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 13:49:44
User entered '186581' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:49:44

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:21
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:35:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:02
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:49:44

US3362166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:40

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)	01 May 2021 20:36:21
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:35:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 19:57:10

US3362166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:40

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)	01 May 2021 20:36:21
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:35:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:02
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 19:57:10

US3362166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:21
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:38:05
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:35:57
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
DataPoint Un-verified.		31 Mar 2021 12:51:44
Signature has been broken.		31 Mar 2021 12:51:44
User entered 'Yes (Y)' reason for change: Data Entry Error		31 Mar 2021 12:51:44
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:02
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 19:57:10

US3362166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:40

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:21
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:35:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 19:57:10

US3362166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:40

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:21
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:35:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:02
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 19:57:10

US3362166

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:11:40

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:36:21
Data hard unlocked.		29 Apr 2021 07:35:57
Data hard locked.		03 Apr 2021 07:44:15
DataPoint Verified.		24 Mar 2021 19:59:48
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:01:42
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:35:25



US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 07:52:34
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:45:01
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:44:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Sep 2020 18:44:57
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:45:56
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '174' cm	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:44:57
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:44:57
DataPoint Verified.		23 Sep 2020 18:49:32
User entered '148.7' kg		17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 07:52:34
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:45:01
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:44:57
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:44:57
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).		24 Sep 2020 12:45:56
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '174' cm	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:44:57
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:44:57
DataPoint Verified.		23 Sep 2020 18:49:32
User entered '148.7' kg		17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '08:09'	(b) (4), (b) (6)	17 Aug 2020 20:00:37



US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered '17 Aug 2020 08:09'	System	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '36.9' C	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '63'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'bpm'	System	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '16'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'breaths/min'	System	17 Aug 2020 20:00:37



US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:49:32
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 16:31:31
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 20:01:07
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Aug 2020 20:00:37
User entered '170'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'mmHg'	System	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '79'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'mmHg'	System	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 07:52:34
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:45:01
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:44:57
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:44:57
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).		24 Sep 2020 12:45:56
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '174' cm	(b) (4), (b) (6)	17 Aug 2020 20:00:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:11:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:44:57
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:44:57
DataPoint Verified.		23 Sep 2020 18:49:32
User entered '148.7' kg		17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 20:00:37



US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 16:31:36
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN PER PROTOCOL' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 20:01:51
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 20:00:37
User entered '09:50'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered '17 Aug 2020 09:50'	System	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '36.9' C	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '62'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'bpm'	System	17 Aug 2020 20:00:37



US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '18'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'breaths/min'	System	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '153'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'mmHg'	System	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:32
User entered '77'	(b) (4), (b) (6)	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'mmHg'	System	17 Aug 2020 20:00:37

US3362166

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 20:07:49

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:11:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:49
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 20:07:49



US3362166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 14:30:55

US3362166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:57
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:30:55

US3362166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:57
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:30:55

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:11:40**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 14:30:55

US3362166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:57
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 14:30:55

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:11:40**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:57
User entered '09:15'	(b) (4), (b) (6)	17 Aug 2020 14:30:55

US3362166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered '17 Aug 2020 09:15'	System	17 Aug 2020 14:30:55

US3362166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:57
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	17 Aug 2020 14:30:55



US3362166

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:49:57
User entered 'ONCE'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:11:40**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 14:30:55

US3362166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:50:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 20:09:47

US3362166

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:50:31
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 20:09:47

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:50:31
User entered '08:38'	(b) (4), (b) (6)	17 Aug 2020 20:09:47

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered '17 Aug 2020 08:38'	System	17 Aug 2020 20:09:47

US3362166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:11:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:50:43
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 20:10:31

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Aug 2020 20:10:31



US3362166

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:50:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 20:10:31

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:50:43
User entered '08:37'	(b) (4), (b) (6)	17 Aug 2020 20:10:31

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered '17 Aug 2020 08:37'	System	17 Aug 2020 20:10:31

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Aug 2020 20:10:31

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:50:43
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 20:10:31

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:50:43
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 20:10:31

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered empty.	System	17 Aug 2020 20:10:31

**US3362166**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:50:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 20:10:39



**US3362166**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'I'	System	17 Aug 2020 20:10:39

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:46:41', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '90eb72d9-41bf-4172-a291-f09c536a7f4d'	System	17 Aug 2020 14:47:10
User entered 'Yes (Y)'	System	17 Aug 2020 14:47:10

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:46:50', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '90eb72d9-41bf-4172-a291-f09c536a7f4d'	System	17 Aug 2020 14:47:10
User entered '98.5'	System	17 Aug 2020 14:47:10

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:46:56', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '90eb72d9-41bf-4172-a291-f09c536a7f4d'	System	17 Aug 2020 14:47:10
User entered 'No (N)'	System	17 Aug 2020 14:47:10

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:47:04', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '90eb72d9-41bf-4172-a291-f09c536a7f4d'	System	17 Aug 2020 14:47:10
User entered '17 Aug 2020 09:47'	System	17 Aug 2020 14:47:10

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Aug 2020 09:35'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 14:30:55



US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:13:58', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1e166b75-b2cb-4c9e-93db-cd5abd5cc641'	System	17 Aug 2020 18:14:24
User entered 'Yes (Y)'	System	17 Aug 2020 18:14:24

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:05', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1e166b75-b2cb-4c9e-93db-cd5abd5cc641'	System	17 Aug 2020 18:14:24
User entered '98.5'	System	17 Aug 2020 18:14:24

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:12', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1e166b75-b2cb-4c9e-93db-cd5abd5cc641'	System	17 Aug 2020 18:14:24
User entered 'No (N)'	System	17 Aug 2020 18:14:24

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:19', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1e166b75-b2cb-4c9e-93db-cd5abd5cc641'	System	17 Aug 2020 18:14:24
User entered '17 Aug 2020 13:14'	System	17 Aug 2020 18:14:24

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Aug 2020 13:00'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 2'	System	17 Aug 2020 14:30:55



US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:27:32', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9dfa46ff-a35a-45b5-8304-9e07947c4024'	System	19 Aug 2020 00:27:53
User entered 'Yes (Y)'	System	19 Aug 2020 00:27:53

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:27:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9dfa46ff-a35a-45b5-8304-9e07947c4024'	System	19 Aug 2020 00:27:53
User entered '98.7'	System	19 Aug 2020 00:27:53

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:27:43', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9dfa46ff-a35a-45b5-8304-9e07947c4024'	System	19 Aug 2020 00:27:53
User entered 'No (N)'	System	19 Aug 2020 00:27:53

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:27:48', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9dfa46ff-a35a-45b5-8304-9e07947c4024'	System	19 Aug 2020 00:27:53
User entered '18 Aug 2020 19:27'	System	19 Aug 2020 00:27:53

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 3'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:17:55', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'b348149f-5bae-4ee1-b24d-c156435cc843'	System	20 Aug 2020 01:18:11
User entered 'Yes (Y)'	System	20 Aug 2020 01:18:11



US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:01', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'b348149f-5bae-4ee1-b24d-c156435cc843'	System	20 Aug 2020 01:18:11
User entered '98.2'	System	20 Aug 2020 01:18:11

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:03', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'b348149f-5bae-4ee1-b24d-c156435cc843'	System	20 Aug 2020 01:18:11
User entered 'No (N)'	System	20 Aug 2020 01:18:11

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:09', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'b348149f-5bae-4ee1-b24d-c156435cc843'	System	20 Aug 2020 01:18:11
User entered '19 Aug 2020 20:18'	System	20 Aug 2020 01:18:11

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 4'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:06', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'c27c021b-3792-4850-a911-7e6d7a95ae36'	System	21 Aug 2020 12:48:23
User entered 'Yes (Y)'	System	21 Aug 2020 12:48:23

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:13', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'c27c021b-3792-4850-a911-7e6d7a95ae36'	System	21 Aug 2020 12:48:23
User entered '98.5'	System	21 Aug 2020 12:48:23



US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:16', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'c27c021b-3792-4850-a911-7e6d7a95ae36'	System	21 Aug 2020 12:48:23
User entered 'No (N)'	System	21 Aug 2020 12:48:23

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'c27c021b-3792-4850-a911-7e6d7a95ae36'	System	21 Aug 2020 12:48:23
User entered '21 Aug 2020 07:48'	System	21 Aug 2020 12:48:23

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 5'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:05', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '5ef9435b-3429-45eb-a0f4-7e885bdb646'	System	22 Aug 2020 14:07:24
User entered 'Yes (Y)'	System	22 Aug 2020 14:07:24

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:13', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '5ef9435b-3429-45eb-a0f4-7e885bdb646'	System	22 Aug 2020 14:07:24
User entered '98.5'	System	22 Aug 2020 14:07:24

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:18', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '5ef9435b-3429-45eb-a0f4-7e885bdb646'	System	22 Aug 2020 14:07:24
User entered 'No (N)'	System	22 Aug 2020 14:07:24



US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:23', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '5ef9435b-3429-45eb-a0f4-7e885bdb646'	System	22 Aug 2020 14:07:24
User entered '22 Aug 2020 09:07'	System	22 Aug 2020 14:07:24

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 6'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:07', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd3641383-cb78-4689-b998-960c567212dc'	System	23 Aug 2020 06:02:23
User entered 'Yes (Y)'	System	23 Aug 2020 06:02:23

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:14', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd3641383-cb78-4689-b998-960c567212dc'	System	23 Aug 2020 06:02:23
User entered '98.5'	System	23 Aug 2020 06:02:23

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:17', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd3641383-cb78-4689-b998-960c567212dc'	System	23 Aug 2020 06:02:23
User entered 'No (N)'	System	23 Aug 2020 06:02:23

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:19', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd3641383-cb78-4689-b998-960c567212dc'	System	23 Aug 2020 06:02:23
User entered '23 Aug 2020 01:02'	System	23 Aug 2020 06:02:23



US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 7'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:15:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a7d12aa-8a0f-41b9-a711-096d33dd08fb'	System	24 Aug 2020 03:15:55
User entered 'Yes (Y)'	System	24 Aug 2020 03:15:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:15:46', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a7d12aa-8a0f-41b9-a711-096d33dd08fb'	System	24 Aug 2020 03:15:55
User entered '97.5'	System	24 Aug 2020 03:15:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:15:48', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a7d12aa-8a0f-41b9-a711-096d33dd08fb'	System	24 Aug 2020 03:15:55
User entered 'No (N)'	System	24 Aug 2020 03:15:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:15:54', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a7d12aa-8a0f-41b9-a711-096d33dd08fb'	System	24 Aug 2020 03:15:55
User entered '23 Aug 2020 22:15'	System	24 Aug 2020 03:15:55

US3362166

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 14:30:55



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:47:41', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '31f780b2-9b5a-4987-8759-6e87b7e41053'	System	17 Aug 2020 14:48:25
User entered 'None (1)'	System	17 Aug 2020 14:48:25

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:47:44', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '31f780b2-9b5a-4987-8759-6e87b7e41053'	System	17 Aug 2020 14:48:25
User entered 'No (N)'	System	17 Aug 2020 14:48:25

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:47:48', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '31f780b2-9b5a-4987-8759-6e87b7e41053'	System	17 Aug 2020 14:48:25
User entered 'No (N)'	System	17 Aug 2020 14:48:25

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:47:56', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '31f780b2-9b5a-4987-8759-6e87b7e41053'	System	17 Aug 2020 14:48:25
User entered 'None (1)'	System	17 Aug 2020 14:48:25

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:48:17', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '31f780b2-9b5a-4987-8759-6e87b7e41053'	System	17 Aug 2020 14:48:25
User entered '17 Aug 2020 09:48'	System	17 Aug 2020 14:48:25

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Aug 2020 09:35'	System	17 Aug 2020 14:30:55



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:29', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '64a5e909-50e3-4e35-a0c1-26fb814bf9a7'	System	17 Aug 2020 18:14:47
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 18:14:47

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:32', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '64a5e909-50e3-4e35-a0c1-26fb814bf9a7'	System	17 Aug 2020 18:14:47
User entered 'No (N)'	System	17 Aug 2020 18:14:47

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:36', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '64a5e909-50e3-4e35-a0c1-26fb814bf9a7'	System	17 Aug 2020 18:14:47
User entered 'No (N)'	System	17 Aug 2020 18:14:47

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:40', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '64a5e909-50e3-4e35-a0c1-26fb814bf9a7'	System	17 Aug 2020 18:14:47
User entered 'None (1)'	System	17 Aug 2020 18:14:47

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:44', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '64a5e909-50e3-4e35-a0c1-26fb814bf9a7'	System	17 Aug 2020 18:14:47
User entered '17 Aug 2020 13:14'	System	17 Aug 2020 18:14:47

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Aug 2020 13:00'	System	17 Aug 2020 14:30:55



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 2'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:28:07', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'eccfe28f-8f34-41f0-81f3-8379727abf90'	System	19 Aug 2020 00:28:42
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 00:28:42

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:28:09', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'eccfe28f-8f34-41f0-81f3-8379727abf90'	System	19 Aug 2020 00:28:42
User entered 'No (N)'	System	19 Aug 2020 00:28:42

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:28:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'eccfe28f-8f34-41f0-81f3-8379727abf90'	System	19 Aug 2020 00:28:42
User entered 'No (N)'	System	19 Aug 2020 00:28:42

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:28:30', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'eccfe28f-8f34-41f0-81f3-8379727abf90'	System	19 Aug 2020 00:28:42
User entered 'None (1)'	System	19 Aug 2020 00:28:42

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:28:37', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'eccfe28f-8f34-41f0-81f3-8379727abf90'	System	19 Aug 2020 00:28:42
User entered '18 Aug 2020 19:28'	System	19 Aug 2020 00:28:42

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 14:30:55



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 3'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:16', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ef90460b-2bfd-458f-849c-04462aec3245'	System	20 Aug 2020 01:18:34
User entered 'None (1)'	System	20 Aug 2020 01:18:34

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:18', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ef90460b-2bfd-458f-849c-04462aec3245'	System	20 Aug 2020 01:18:34
User entered 'No (N)'	System	20 Aug 2020 01:18:34

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ef90460b-2bfd-458f-849c-04462aec3245'	System	20 Aug 2020 01:18:34
User entered 'No (N)'	System	20 Aug 2020 01:18:34

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:23', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ef90460b-2bfd-458f-849c-04462aec3245'	System	20 Aug 2020 01:18:34
User entered 'None (1)'	System	20 Aug 2020 01:18:34

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ef90460b-2bfd-458f-849c-04462aec3245'	System	20 Aug 2020 01:18:34
User entered '19 Aug 2020 20:18'	System	20 Aug 2020 01:18:34

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 14:30:55



US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 4'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:25', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '058e99e9-60b2-40fc-9c69-656b441ed323'	System	21 Aug 2020 12:48:36
User entered 'None (1)'	System	21 Aug 2020 12:48:36

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:27', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '058e99e9-60b2-40fc-9c69-656b441ed323'	System	21 Aug 2020 12:48:36
User entered 'No (N)'	System	21 Aug 2020 12:48:36

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:29', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '058e99e9-60b2-40fc-9c69-656b441ed323'	System	21 Aug 2020 12:48:36
User entered 'No (N)'	System	21 Aug 2020 12:48:36

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:32', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '058e99e9-60b2-40fc-9c69-656b441ed323'	System	21 Aug 2020 12:48:36
User entered 'None (1)'	System	21 Aug 2020 12:48:36

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:34', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '058e99e9-60b2-40fc-9c69-656b441ed323'	System	21 Aug 2020 12:48:36
User entered '21 Aug 2020 07:48'	System	21 Aug 2020 12:48:36

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 14:30:55



US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 5'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'cef24bce-2890-4ad8-9442-0244044ed2e7'	System	22 Aug 2020 14:07:40
User entered 'None (1)'	System	22 Aug 2020 14:07:40

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:30', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'cef24bce-2890-4ad8-9442-0244044ed2e7'	System	22 Aug 2020 14:07:40
User entered 'No (N)'	System	22 Aug 2020 14:07:40

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:32', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'cef24bce-2890-4ad8-9442-0244044ed2e7'	System	22 Aug 2020 14:07:40
User entered 'No (N)'	System	22 Aug 2020 14:07:40

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:35', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'cef24bce-2890-4ad8-9442-0244044ed2e7'	System	22 Aug 2020 14:07:40
User entered 'None (1)'	System	22 Aug 2020 14:07:40

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:38', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'cef24bce-2890-4ad8-9442-0244044ed2e7'	System	22 Aug 2020 14:07:40
User entered '22 Aug 2020 09:07'	System	22 Aug 2020 14:07:40

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 14:30:55



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 6'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:23', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'a891cbce-c98e-421d-a64c-2bf1cd49e2ce'	System	23 Aug 2020 06:02:35
User entered 'None (1)'	System	23 Aug 2020 06:02:35

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:25', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'a891cbce-c98e-421d-a64c-2bf1cd49e2ce'	System	23 Aug 2020 06:02:35
User entered 'No (N)'	System	23 Aug 2020 06:02:35

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:27', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'a891cbce-c98e-421d-a64c-2bf1cd49e2ce'	System	23 Aug 2020 06:02:35
User entered 'No (N)'	System	23 Aug 2020 06:02:35

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:31', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'a891cbce-c98e-421d-a64c-2bf1cd49e2ce'	System	23 Aug 2020 06:02:35
User entered 'None (1)'	System	23 Aug 2020 06:02:35

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:34', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'a891cbce-c98e-421d-a64c-2bf1cd49e2ce'	System	23 Aug 2020 06:02:35
User entered '23 Aug 2020 01:02'	System	23 Aug 2020 06:02:35

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 14:30:55



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 7'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:15:58', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e62bc756-b17d-450d-85a8-685dc376bb22'	System	24 Aug 2020 03:16:13
User entered 'None (1)'	System	24 Aug 2020 03:16:13

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:02', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e62bc756-b17d-450d-85a8-685dc376bb22'	System	24 Aug 2020 03:16:13
User entered 'No (N)'	System	24 Aug 2020 03:16:13

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:08', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e62bc756-b17d-450d-85a8-685dc376bb22'	System	24 Aug 2020 03:16:13
User entered 'No (N)'	System	24 Aug 2020 03:16:13

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:10', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e62bc756-b17d-450d-85a8-685dc376bb22'	System	24 Aug 2020 03:16:13
User entered 'None (1)'	System	24 Aug 2020 03:16:13

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:12', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e62bc756-b17d-450d-85a8-685dc376bb22'	System	24 Aug 2020 03:16:13
User entered '23 Aug 2020 22:16'	System	24 Aug 2020 03:16:13

US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 14:30:55



US3362166

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:48:25', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e3c70291-9af9-42dc-9c6a-4f3a62909a93'	System	17 Aug 2020 14:48:53
User entered 'None (0)'	System	17 Aug 2020 14:48:53

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:48:27', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e3c70291-9af9-42dc-9c6a-4f3a62909a93'	System	17 Aug 2020 14:48:53
User entered 'None (0)'	System	17 Aug 2020 14:48:53

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:48:30', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e3c70291-9af9-42dc-9c6a-4f3a62909a93'	System	17 Aug 2020 14:48:53
User entered 'None (0)'	System	17 Aug 2020 14:48:53

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:48:32', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e3c70291-9af9-42dc-9c6a-4f3a62909a93'	System	17 Aug 2020 14:48:53
User entered 'None (0)'	System	17 Aug 2020 14:48:53

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:48:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e3c70291-9af9-42dc-9c6a-4f3a62909a93'	System	17 Aug 2020 14:48:53
User entered 'None (0)'	System	17 Aug 2020 14:48:53

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:48:41', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e3c70291-9af9-42dc-9c6a-4f3a62909a93'	System	17 Aug 2020 14:48:53
User entered 'None (0)'	System	17 Aug 2020 14:48:53



US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:48:47', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e3c70291-9af9-42dc-9c6a-4f3a62909a93'	System	17 Aug 2020 14:48:53
User entered 'No (N)'	System	17 Aug 2020 14:48:53

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T09:48:50', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e3c70291-9af9-42dc-9c6a-4f3a62909a93'	System	17 Aug 2020 14:48:53
User entered '17 Aug 2020 09:48'	System	17 Aug 2020 14:48:53

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Aug 2020 09:35'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:49', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bd2ef00-7121-4220-92b8-eca2aed1cf19'	System	17 Aug 2020 18:15:12
User entered 'None (0)'	System	17 Aug 2020 18:15:12

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:51', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bd2ef00-7121-4220-92b8-eca2aed1cf19'	System	17 Aug 2020 18:15:12
User entered 'None (0)'	System	17 Aug 2020 18:15:12

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:53', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bd2ef00-7121-4220-92b8-eca2aed1cf19'	System	17 Aug 2020 18:15:12
User entered 'None (0)'	System	17 Aug 2020 18:15:12



US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:55', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bd2ef00-7121-4220-92b8-eca2aed1cf19'	System	17 Aug 2020 18:15:12
User entered 'None (0)'	System	17 Aug 2020 18:15:12

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:14:59', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bd2ef00-7121-4220-92b8-eca2aed1cf19'	System	17 Aug 2020 18:15:12
User entered 'None (0)'	System	17 Aug 2020 18:15:12

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:15:01', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bd2ef00-7121-4220-92b8-eca2aed1cf19'	System	17 Aug 2020 18:15:12
User entered 'None (0)'	System	17 Aug 2020 18:15:12

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:15:05', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bd2ef00-7121-4220-92b8-eca2aed1cf19'	System	17 Aug 2020 18:15:12
User entered 'No (N)'	System	17 Aug 2020 18:15:12

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-17T13:15:09', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bd2ef00-7121-4220-92b8-eca2aed1cf19'	System	17 Aug 2020 18:15:12
User entered '17 Aug 2020 13:15'	System	17 Aug 2020 18:15:12

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Aug 2020 13:00'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 2'	System	17 Aug 2020 14:30:55



US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:28:43', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85147f03-9950-437e-ae38-c6db96d6918c'	System	19 Aug 2020 00:29:13
User entered 'None (0)'	System	19 Aug 2020 00:29:13

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:28:46', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85147f03-9950-437e-ae38-c6db96d6918c'	System	19 Aug 2020 00:29:13
User entered 'None (0)'	System	19 Aug 2020 00:29:13

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:28:55', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85147f03-9950-437e-ae38-c6db96d6918c'	System	19 Aug 2020 00:29:13
User entered 'No interference with activity (1)'	System	19 Aug 2020 00:29:13

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:28:59', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85147f03-9950-437e-ae38-c6db96d6918c'	System	19 Aug 2020 00:29:13
User entered 'None (0)'	System	19 Aug 2020 00:29:13

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:29:02', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85147f03-9950-437e-ae38-c6db96d6918c'	System	19 Aug 2020 00:29:13
User entered 'None (0)'	System	19 Aug 2020 00:29:13

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:29:04', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85147f03-9950-437e-ae38-c6db96d6918c'	System	19 Aug 2020 00:29:13
User entered 'None (0)'	System	19 Aug 2020 00:29:13

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:29:07', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85147f03-9950-437e-ae38-c6db96d6918c'	System	19 Aug 2020 00:29:13
User entered 'No (N)'	System	19 Aug 2020 00:29:13

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-18T19:29:10', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85147f03-9950-437e-ae38-c6db96d6918c'	System	19 Aug 2020 00:29:13
User entered '18 Aug 2020 19:29'	System	19 Aug 2020 00:29:13



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 3'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:32', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1935ff8e-00b4-4f79-b3ee-fe34063502cc'	System	20 Aug 2020 01:18:57
User entered 'None (0)'	System	20 Aug 2020 01:18:57

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:35', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1935ff8e-00b4-4f79-b3ee-fe34063502cc'	System	20 Aug 2020 01:18:57
User entered 'None (0)'	System	20 Aug 2020 01:18:57

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:36', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1935ff8e-00b4-4f79-b3ee-fe34063502cc'	System	20 Aug 2020 01:18:57
User entered 'None (0)'	System	20 Aug 2020 01:18:57

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:38', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1935ff8e-00b4-4f79-b3ee-fe34063502cc'	System	20 Aug 2020 01:18:57
User entered 'None (0)'	System	20 Aug 2020 01:18:57

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:40', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1935ff8e-00b4-4f79-b3ee-fe34063502cc'	System	20 Aug 2020 01:18:57
User entered 'None (0)'	System	20 Aug 2020 01:18:57



US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:42', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1935ff8e-00b4-4f79-b3ee-fe34063502cc'	System	20 Aug 2020 01:18:57
User entered 'None (0)'	System	20 Aug 2020 01:18:57

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:47', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1935ff8e-00b4-4f79-b3ee-fe34063502cc'	System	20 Aug 2020 01:18:57
User entered 'No (N)'	System	20 Aug 2020 01:18:57

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-19T20:18:53', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1935ff8e-00b4-4f79-b3ee-fe34063502cc'	System	20 Aug 2020 01:18:57
User entered '19 Aug 2020 20:18'	System	20 Aug 2020 01:18:57

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 4'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:47:59', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd6763398-932f-4eb4-a3ed-53e0f2bbaf24'	System	21 Aug 2020 12:48:04
User entered 'None (0)'	System	21 Aug 2020 12:48:04

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:47:38', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd6763398-932f-4eb4-a3ed-53e0f2bbaf24'	System	21 Aug 2020 12:48:04
User entered 'None (0)'	System	21 Aug 2020 12:48:04



US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:47:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd6763398-932f-4eb4-a3ed-53e0f2bbaf24'	System	21 Aug 2020 12:48:04
User entered 'None (0)'	System	21 Aug 2020 12:48:04

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:47:41', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd6763398-932f-4eb4-a3ed-53e0f2bbaf24'	System	21 Aug 2020 12:48:04
User entered 'None (0)'	System	21 Aug 2020 12:48:04

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:47:51', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd6763398-932f-4eb4-a3ed-53e0f2bbaf24'	System	21 Aug 2020 12:48:04
User entered 'None (0)'	System	21 Aug 2020 12:48:04

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:47:53', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd6763398-932f-4eb4-a3ed-53e0f2bbaf24'	System	21 Aug 2020 12:48:04
User entered 'None (0)'	System	21 Aug 2020 12:48:04

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:47:55', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd6763398-932f-4eb4-a3ed-53e0f2bbaf24'	System	21 Aug 2020 12:48:04
User entered 'No (N)'	System	21 Aug 2020 12:48:04

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-21T07:48:02', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'd6763398-932f-4eb4-a3ed-53e0f2bbaf24'	System	21 Aug 2020 12:48:04
User entered '21 Aug 2020 07:48'	System	21 Aug 2020 12:48:04

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 14:30:55



US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 5'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:42', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85b325af-e365-4f07-85fb-ec920efd5b2e'	System	22 Aug 2020 14:07:59
User entered 'None (0)'	System	22 Aug 2020 14:07:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:44', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85b325af-e365-4f07-85fb-ec920efd5b2e'	System	22 Aug 2020 14:07:59
User entered 'None (0)'	System	22 Aug 2020 14:07:59

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:45', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85b325af-e365-4f07-85fb-ec920efd5b2e'	System	22 Aug 2020 14:07:59
User entered 'None (0)'	System	22 Aug 2020 14:07:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:47', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85b325af-e365-4f07-85fb-ec920efd5b2e'	System	22 Aug 2020 14:07:59
User entered 'None (0)'	System	22 Aug 2020 14:07:59

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:49', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85b325af-e365-4f07-85fb-ec920efd5b2e'	System	22 Aug 2020 14:07:59
User entered 'None (0)'	System	22 Aug 2020 14:07:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:51', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85b325af-e365-4f07-85fb-ec920efd5b2e'	System	22 Aug 2020 14:07:59
User entered 'None (0)'	System	22 Aug 2020 14:07:59

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:53', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85b325af-e365-4f07-85fb-ec920efd5b2e'	System	22 Aug 2020 14:07:59
User entered 'No (N)'	System	22 Aug 2020 14:07:59



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-22T09:07:57', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '85b325af-e365-4f07-85fb-ec920efd5b2e'	System	22 Aug 2020 14:07:59
User entered '22 Aug 2020 09:07'	System	22 Aug 2020 14:07:59

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 6'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:44', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '86519eab-9f1a-48f8-bc1f-e868cadf88a0'	System	23 Aug 2020 06:03:02
User entered 'No interference with activity (1)'	System	23 Aug 2020 06:03:02

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:46', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '86519eab-9f1a-48f8-bc1f-e868cadf88a0'	System	23 Aug 2020 06:03:02
User entered 'None (0)'	System	23 Aug 2020 06:03:02

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:48', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '86519eab-9f1a-48f8-bc1f-e868cadf88a0'	System	23 Aug 2020 06:03:02
User entered 'None (0)'	System	23 Aug 2020 06:03:02

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:49', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '86519eab-9f1a-48f8-bc1f-e868cadf88a0'	System	23 Aug 2020 06:03:02
User entered 'None (0)'	System	23 Aug 2020 06:03:02



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:52', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '86519eab-9f1a-48f8-bc1f-e868cadf88a0'	System	23 Aug 2020 06:03:02
User entered 'None (0)'	System	23 Aug 2020 06:03:02

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:54', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '86519eab-9f1a-48f8-bc1f-e868cadf88a0'	System	23 Aug 2020 06:03:02
User entered 'None (0)'	System	23 Aug 2020 06:03:02

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:02:57', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '86519eab-9f1a-48f8-bc1f-e868cadf88a0'	System	23 Aug 2020 06:03:02
User entered 'No (N)'	System	23 Aug 2020 06:03:02

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T01:03:01', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '86519eab-9f1a-48f8-bc1f-e868cadf88a0'	System	23 Aug 2020 06:03:02
User entered '23 Aug 2020 01:03'	System	23 Aug 2020 06:03:02

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 7'	System	17 Aug 2020 14:30:55

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:17', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '8af3b030-9fdb-4c05-a5e7-a118e8f18046'	System	24 Aug 2020 03:16:33
User entered 'None (0)'	System	24 Aug 2020 03:16:33



US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:19', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '8af3b030-9fdb-4c05-a5e7-a118e8f18046'	System	24 Aug 2020 03:16:33
User entered 'None (0)'	System	24 Aug 2020 03:16:33

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '8af3b030-9fdb-4c05-a5e7-a118e8f18046'	System	24 Aug 2020 03:16:33
User entered 'None (0)'	System	24 Aug 2020 03:16:33

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:23', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '8af3b030-9fdb-4c05-a5e7-a118e8f18046'	System	24 Aug 2020 03:16:33
User entered 'None (0)'	System	24 Aug 2020 03:16:33

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:24', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '8af3b030-9fdb-4c05-a5e7-a118e8f18046'	System	24 Aug 2020 03:16:33
User entered 'None (0)'	System	24 Aug 2020 03:16:33

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:25', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '8af3b030-9fdb-4c05-a5e7-a118e8f18046'	System	24 Aug 2020 03:16:33
User entered 'None (0)'	System	24 Aug 2020 03:16:33

US3362166

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '8af3b030-9fdb-4c05-a5e7-a118e8f18046'	System	24 Aug 2020 03:16:33
User entered 'No (N)'	System	24 Aug 2020 03:16:33

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-08-23T22:16:31', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '8af3b030-9fdb-4c05-a5e7-a118e8f18046'	System	24 Aug 2020 03:16:33
User entered '23 Aug 2020 22:16'	System	24 Aug 2020 03:16:33

**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 14:30:55



**US3362166**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 22:51:49

**US3362166**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:00
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 22:51:49

**US3362166**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Aug 2020 22:51:49

US3362166

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:00
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 22:51:49

**US3362166**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 22:52:01

**US3362166**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'I'	System	24 Aug 2020 22:52:01

**US3362166**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:04:59
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:22
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	31 Aug 2020 20:50:36



**US3362166**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:04:59
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:22
User entered '31 Aug 2020'	Crystal Rowell (b) (4)	31 Aug 2020 20:50:36

**US3362166**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:04:59
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:22
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4)	31 Aug 2020 20:50:36

**US3362166**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:04:59
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:22
User entered empty.	Crystal Rowell (b) (4)	31 Aug 2020 20:50:36

US3362166

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:04:59
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:56:27
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	31 Aug 2020 20:50:42

**US3362166**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:44:15
User entered 'I'	System	31 Aug 2020 20:50:42

**US3362166**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:57:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:14:26

**US3362166**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:57:12
User entered '8 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:14:26

**US3362166**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:57:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 14:14:26



US3362166

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:57:12
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:14:26

**US3362166**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:04:59
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:57:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:14:32

**US3362166**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'I'	System	14 Sep 2020 14:14:32

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:04:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:09
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:04:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:09
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Sep 2020 15:04:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'VISIT2'	System	14 Sep 2020 15:04:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Sep 2020 15:02:41



US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '08:10'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered '14 Sep 2020 08:10'	System	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '36.7' C	(b) (4), (b) (6)	14 Sep 2020 15:02:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:11:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:02:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '64'	(b) (4), (b) (6)	14 Sep 2020 15:02:41



**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'bpm'	System	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '16'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'breaths/min'	System	14 Sep 2020 15:02:41

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 19:03:18
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS, history of hypertension on meds' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 15:03:57
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 15:02:41
User entered '163'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'mmHg'	System	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '91'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:11:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'mmHg'	System	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Sep 2020 15:02:41



US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '09:48'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered '14 Sep 2020 09:48'	System	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '36.8' C	(b) (4), (b) (6)	14 Sep 2020 15:02:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:02:41

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '59'	(b) (4), (b) (6)	14 Sep 2020 15:02:41



**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'bpm'	System	14 Sep 2020 15:02:41

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '18'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'breaths/min'	System	14 Sep 2020 15:02:41

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 18:54:06
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 19:03:33
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS, history of hypertension, on meds' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 15:04:32
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	14 Sep 2020 15:02:41
User entered '160'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'mmHg'	System	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:06
User entered '92'	(b) (4), (b) (6)	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:11:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'mmHg'	System	14 Sep 2020 15:02:41

US3362166

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:05:39



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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:13
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:05:39

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:15:03

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:19
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:15:03

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

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)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:19
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:15:03

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:11:40**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 14:15:03

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:19
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:15:03

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:11:40**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:19
User entered '09:10'	(b) (4), (b) (6)	14 Sep 2020 14:15:03

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:11:40**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered '14 Sep 2020 09:10'	System	14 Sep 2020 14:15:03



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:19
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Sep 2020 14:15:03

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:19
User entered 'ONCE'	System	14 Sep 2020 14:15:03

US3362166

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:11:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 14:15:03

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:05:56

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'site did not have V2D29 kit inventory. Therefore, unscheduled kits were used. Data change request form will be submitted to PPD' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 12:25:23
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). DataPoint Verified.	Amy Thomassie (b) (4) (b) (4)	31 Oct 2020 14:16:47
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:20:13
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:56
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:05:56

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:54:56
User entered '08:24'	(b) (4), (b) (6)	14 Sep 2020 15:05:56

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered '14 Sep 2020 08:24'	System	14 Sep 2020 15:05:56

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:11:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is an Unscheduled Swab sample with a Collection Date of 14SEP2020, however, per Viracor, the Swab sample with a Collection Date of 14SEP2020 is recorded under Visit 1 Day 1. Please confirm the correct Visit Name in the query response, as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 19:00:46
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, Amy Thomassie there is an Unscheduled Swab sample with a Collection Date of 14SEP2020, however, per Viracor, the Swab sample with a Collection Date of 14SEP2020 is recorded under Visit 1 Day 1. Please confirm the correct Visit Name in the query response, as appropriate. ' answered with 'Visit 2 Day 29' (Site from DM).	(b) (4) (b) (4)	08 Jan 2021 21:31:21
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is an Unscheduled Swab sample with a Collection Date of 14SEP2020, however, per Viracor, the Swab sample with a Collection Date of 14SEP2020 is recorded under Visit 1 Day 1. Please confirm the correct Visit Name in the query response, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 18:40:12
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:38:59



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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:11:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'DELAY IN LAB KIT SHIPMENT. PER SPONSER, APPROVED TO USE UNSCHEDULED LAB KIT FOR VISIT 2' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:57:27
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:10:02
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:55:07
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:06:10

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Sep 2020 15:06:10

US3362166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:11:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:55:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:06:10

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:55:07
User entered '08:21'	(b) (4), (b) (6)	14 Sep 2020 15:06:10

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered '14 Sep 2020 08:21'	System	14 Sep 2020 15:06:10

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Sep 2020 15:06:10

US3362166

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:11:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:55:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 15:06:10

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:55:07
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:06:10



**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered empty.	System	14 Sep 2020 15:06:10

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:55:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:08:04

**US3362166**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'I'	System	14 Sep 2020 15:08:04

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:43:07', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '34e87b5e-0b70-433d-b9ad-e26ecd8532a3'	System	14 Sep 2020 14:43:23
User entered 'Yes (Y)'	System	14 Sep 2020 14:43:23

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:43:13', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '34e87b5e-0b70-433d-b9ad-e26ecd8532a3'	System	14 Sep 2020 14:43:23
User entered '98.2'	System	14 Sep 2020 14:43:23

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:43:16', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '34e87b5e-0b70-433d-b9ad-e26ecd8532a3'	System	14 Sep 2020 14:43:23
User entered 'No (N)'	System	14 Sep 2020 14:43:23

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:43:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '34e87b5e-0b70-433d-b9ad-e26ecd8532a3'	System	14 Sep 2020 14:43:23
User entered '14 Sep 2020 09:43'	System	14 Sep 2020 14:43:23



**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '14 Sep 2020 09:30'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:56:34', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e371a630-ba44-45f6-a430-38deb238171b'	System	15 Sep 2020 00:56:51
User entered 'Yes (Y)'	System	15 Sep 2020 00:56:51

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:56:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e371a630-ba44-45f6-a430-38deb238171b'	System	15 Sep 2020 00:56:51
User entered '98.3'	System	15 Sep 2020 00:56:51

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:56:43', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e371a630-ba44-45f6-a430-38deb238171b'	System	15 Sep 2020 00:56:51
User entered 'No (N)'	System	15 Sep 2020 00:56:51

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:56:49', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e371a630-ba44-45f6-a430-38deb238171b'	System	15 Sep 2020 00:56:51
User entered '14 Sep 2020 19:56'	System	15 Sep 2020 00:56:51

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '14 Sep 2020 12:55'	System	14 Sep 2020 14:15:03



US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 2'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:49:26', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '722dcee3-319d-4da3-bdeb-2a128a0ccdcdb'	System	15 Sep 2020 23:50:18
User entered 'Yes (Y)'	System	15 Sep 2020 23:50:18

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:49:30', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '722dcee3-319d-4da3-bdeb-2a128a0ccdcdb' User entered '99.1'	System	15 Sep 2020 23:50:18
	System	15 Sep 2020 23:50:18

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:49:33', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '722dcee3-319d-4da3-bdeb-2a128a0ccdc'b'	System	15 Sep 2020 23:50:18
User entered 'No (N)'	System	15 Sep 2020 23:50:18

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:49:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '722dcee3-319d-4da3-bdeb-2a128a0ccdcdb'	System	15 Sep 2020 23:50:18
User entered '15 Sep 2020 18:49'	System	15 Sep 2020 23:50:18

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 14:15:03



US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 3'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:08', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e20beb36-2dc8-49ee-94c9-1785ce396dc5'	System	16 Sep 2020 22:22:21
User entered 'Yes (Y)'	System	16 Sep 2020 22:22:21

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:12', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e20beb36-2dc8-49ee-94c9-1785ce396dc5'	System	16 Sep 2020 22:22:21
User entered '98.8'	System	16 Sep 2020 22:22:21

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:14', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e20beb36-2dc8-49ee-94c9-1785ce396dc5'	System	16 Sep 2020 22:22:21
User entered 'No (N)'	System	16 Sep 2020 22:22:21

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:18', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e20beb36-2dc8-49ee-94c9-1785ce396dc5'	System	16 Sep 2020 22:22:21
User entered '16 Sep 2020 17:22'	System	16 Sep 2020 22:22:21

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 4'	System	14 Sep 2020 14:15:03



US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:14', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f28634da-7430-4d1f-907f-6594d738be53'	System	18 Sep 2020 02:19:28
User entered 'Yes (Y)'	System	18 Sep 2020 02:19:28

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:19', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f28634da-7430-4d1f-907f-6594d738be53'	System	18 Sep 2020 02:19:28
User entered '98.0'	System	18 Sep 2020 02:19:28

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f28634da-7430-4d1f-907f-6594d738be53'	System	18 Sep 2020 02:19:28
User entered 'No (N)'	System	18 Sep 2020 02:19:28

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:26', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f28634da-7430-4d1f-907f-6594d738be53'	System	18 Sep 2020 02:19:28
User entered '17 Sep 2020 21:19'	System	18 Sep 2020 02:19:28

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 5'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:42:29', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6293d052-b433-4b9d-ba09-0df00622887c'	System	19 Sep 2020 05:42:45
User entered 'Yes (Y)'	System	19 Sep 2020 05:42:45



US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:42:37', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6293d052-b433-4b9d-ba09-0df00622887c' User entered '98.8'	System	19 Sep 2020 05:42:45
	System	19 Sep 2020 05:42:45

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:42:40', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6293d052-b433-4b9d-ba09-0df00622887c'	System	19 Sep 2020 05:42:45
User entered 'No (N)'	System	19 Sep 2020 05:42:45

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:11:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:42:43', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6293d052-b433-4b9d-ba09-0df00622887c'	System	19 Sep 2020 05:42:45
User entered '19 Sep 2020 00:42'	System	19 Sep 2020 05:42:45

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 6'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:15', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'dd6d7e59-aabc-481d-b269-89da1002ff80'	System	19 Sep 2020 17:22:28
User entered 'Yes (Y)'	System	19 Sep 2020 17:22:28

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:19', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'dd6d7e59-aabc-481d-b269-89da1002ff80'	System	19 Sep 2020 17:22:28
User entered '98.6'	System	19 Sep 2020 17:22:28



US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'dd6d7e59-aabc-481d-b269-89da1002ff80'	System	19 Sep 2020 17:22:28
User entered 'No (N)'	System	19 Sep 2020 17:22:28

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:24', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'dd6d7e59-aabc-481d-b269-89da1002ff80'	System	19 Sep 2020 17:22:28
User entered '19 Sep 2020 12:22'	System	19 Sep 2020 17:22:28

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:11:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 7'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:07', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'edd796cb-f15f-404e-ab6d-2db48c5272c0'	System	20 Sep 2020 20:45:33
User entered 'Yes (Y)'	System	20 Sep 2020 20:45:33

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'edd796cb-f15f-404e-ab6d-2db48c5272c0'	System	20 Sep 2020 20:45:33
User entered '98.2'	System	20 Sep 2020 20:45:33

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:24', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'edd796cb-f15f-404e-ab6d-2db48c5272c0'	System	20 Sep 2020 20:45:33
User entered 'No (N)'	System	20 Sep 2020 20:45:33



**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:27', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'edd796cb-f15f-404e-ab6d-2db48c5272c0'	System	20 Sep 2020 20:45:33
User entered '20 Sep 2020 15:45'	System	20 Sep 2020 20:45:33

US3362166

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:45:16', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '05d0b239-8938-4c78-88e6-2f1b6328b548'	System	14 Sep 2020 14:45:57
User entered 'None (1)'	System	14 Sep 2020 14:45:57

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:45:37', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '05d0b239-8938-4c78-88e6-2f1b6328b548'	System	14 Sep 2020 14:45:57
User entered 'No (N)'	System	14 Sep 2020 14:45:57

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:45:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '05d0b239-8938-4c78-88e6-2f1b6328b548'	System	14 Sep 2020 14:45:57
User entered 'No (N)'	System	14 Sep 2020 14:45:57

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:45:44', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '05d0b239-8938-4c78-88e6-2f1b6328b548'	System	14 Sep 2020 14:45:57
User entered 'None (1)'	System	14 Sep 2020 14:45:57



**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:45:47', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '05d0b239-8938-4c78-88e6-2f1b6328b548'	System	14 Sep 2020 14:45:57
User entered '14 Sep 2020 09:45'	System	14 Sep 2020 14:45:57

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '14 Sep 2020 09:30'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:56:58', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '3d849a06-da32-4889-bbc8-3fbdd0cc72e2'	System	15 Sep 2020 01:00:00
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 01:00:00

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:57:05', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '3d849a06-da32-4889-bbc8-3fbdd0cc72e2'	System	15 Sep 2020 01:00:00
User entered 'No (N)'	System	15 Sep 2020 01:00:00

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:57:08', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '3d849a06-da32-4889-bbc8-3fbdd0cc72e2'	System	15 Sep 2020 01:00:00
User entered 'Yes (Y)'	System	15 Sep 2020 01:00:00

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:59:25', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '3d849a06-da32-4889-bbc8-3fbdd0cc72e2'	System	15 Sep 2020 01:00:00
User entered '14'	System	15 Sep 2020 01:00:00



US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:59:51', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '3d849a06-da32-4889-bbc8-3fbdd0cc72e2'	System	15 Sep 2020 01:00:00
User entered 'None (1)'	System	15 Sep 2020 01:00:00

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T19:59:56', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '3d849a06-da32-4889-bbc8-3fbdd0cc72e2'	System	15 Sep 2020 01:00:00
User entered '14 Sep 2020 19:59'	System	15 Sep 2020 01:00:00

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '14 Sep 2020 12:55'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 2'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:49:45', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '2272fc7d-f481-4d44-8782-646f84671b09'	System	15 Sep 2020 23:50:38
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 23:50:38

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:49:47', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '2272fc7d-f481-4d44-8782-646f84671b09'	System	15 Sep 2020 23:50:38
User entered 'No (N)'	System	15 Sep 2020 23:50:38

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:49:51', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '2272fc7d-f481-4d44-8782-646f84671b09'	System	15 Sep 2020 23:50:38
User entered 'Yes (Y)'	System	15 Sep 2020 23:50:38



US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:02', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '2272fc7d-f481-4d44-8782-646f84671b09'	System	15 Sep 2020 23:50:38
User entered '10'	System	15 Sep 2020 23:50:38

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:11:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:07', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '2272fc7d-f481-4d44-8782-646f84671b09'	System	15 Sep 2020 23:50:38
User entered 'None (1)'	System	15 Sep 2020 23:50:38

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:13', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '2272fc7d-f481-4d44-8782-646f84671b09'	System	15 Sep 2020 23:50:38
User entered '15 Sep 2020 18:50'	System	15 Sep 2020 23:50:38

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 3'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:31', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1348b8f9-815e-4a6b-8882-cc61e431b74f'	System	16 Sep 2020 22:22:42
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 22:22:42

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:33', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1348b8f9-815e-4a6b-8882-cc61e431b74f'	System	16 Sep 2020 22:22:42
User entered 'No (N)'	System	16 Sep 2020 22:22:42



US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:35', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1348b8f9-815e-4a6b-8882-cc61e431b74f'	System	16 Sep 2020 22:22:42
User entered 'No (N)'	System	16 Sep 2020 22:22:42

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:11:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:38', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1348b8f9-815e-4a6b-8882-cc61e431b74f'	System	16 Sep 2020 22:22:42
User entered 'None (1)'	System	16 Sep 2020 22:22:42

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:41', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1348b8f9-815e-4a6b-8882-cc61e431b74f'	System	16 Sep 2020 22:22:42
User entered '16 Sep 2020 17:22'	System	16 Sep 2020 22:22:42

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 4'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:31', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e1f3e3cc-fc62-4aef-abd1-8a844f07da9b'	System	18 Sep 2020 02:19:46
User entered 'None (1)'	System	18 Sep 2020 02:19:46

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:34', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e1f3e3cc-fc62-4aef-abd1-8a844f07da9b'	System	18 Sep 2020 02:19:46
User entered 'No (N)'	System	18 Sep 2020 02:19:46



US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:37', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e1f3e3cc-fc62-4aef-abd1-8a844f07da9b'	System	18 Sep 2020 02:19:46
User entered 'No (N)'	System	18 Sep 2020 02:19:46

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e1f3e3cc-fc62-4aef-abd1-8a844f07da9b'	System	18 Sep 2020 02:19:46
User entered 'None (1)'	System	18 Sep 2020 02:19:46

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:43', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e1f3e3cc-fc62-4aef-abd1-8a844f07da9b'	System	18 Sep 2020 02:19:46
User entered '17 Sep 2020 21:19'	System	18 Sep 2020 02:19:46

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:11:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 5'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:42:46', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '461f805e-6871-4308-a621-2c8483666c96'	System	19 Sep 2020 05:42:57
User entered 'None (1)'	System	19 Sep 2020 05:42:57

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:42:49', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '461f805e-6871-4308-a621-2c8483666c96'	System	19 Sep 2020 05:42:57
User entered 'No (N)'	System	19 Sep 2020 05:42:57



US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:42:50', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '461f805e-6871-4308-a621-2c8483666c96'	System	19 Sep 2020 05:42:57
User entered 'No (N)'	System	19 Sep 2020 05:42:57

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:11:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:42:52', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '461f805e-6871-4308-a621-2c8483666c96'	System	19 Sep 2020 05:42:57
User entered 'None (1)'	System	19 Sep 2020 05:42:57

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:42:55', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '461f805e-6871-4308-a621-2c8483666c96'	System	19 Sep 2020 05:42:57
User entered '19 Sep 2020 00:42'	System	19 Sep 2020 05:42:57

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 6'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bf19536-31bb-4503-a9a4-6974cd79ec67'	System	19 Sep 2020 17:22:39
User entered 'None (1)'	System	19 Sep 2020 17:22:39

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:30', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bf19536-31bb-4503-a9a4-6974cd79ec67'	System	19 Sep 2020 17:22:39
User entered 'No (N)'	System	19 Sep 2020 17:22:39



US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:32', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bf19536-31bb-4503-a9a4-6974cd79ec67'	System	19 Sep 2020 17:22:39
User entered 'No (N)'	System	19 Sep 2020 17:22:39

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:11:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:33', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bf19536-31bb-4503-a9a4-6974cd79ec67'	System	19 Sep 2020 17:22:39
User entered 'None (1)'	System	19 Sep 2020 17:22:39

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:36', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1bf19536-31bb-4503-a9a4-6974cd79ec67'	System	19 Sep 2020 17:22:39
User entered '19 Sep 2020 12:22'	System	19 Sep 2020 17:22:39

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 7'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:34', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '4db93428-5624-47f2-b817-cc3313cdd9c0'	System	20 Sep 2020 20:45:48
User entered 'None (1)'	System	20 Sep 2020 20:45:48

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:36', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '4db93428-5624-47f2-b817-cc3313cdd9c0'	System	20 Sep 2020 20:45:48
User entered 'No (N)'	System	20 Sep 2020 20:45:48



US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:38', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '4db93428-5624-47f2-b817-cc3313cdd9c0'	System	20 Sep 2020 20:45:48
User entered 'No (N)'	System	20 Sep 2020 20:45:48

US3362166

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:11:40

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '4db93428-5624-47f2-b817-cc3313cdd9c0'	System	20 Sep 2020 20:45:48
User entered 'None (1)'	System	20 Sep 2020 20:45:48

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:42', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '4db93428-5624-47f2-b817-cc3313cdd9c0'	System	20 Sep 2020 20:45:48
User entered '20 Sep 2020 15:45'	System	20 Sep 2020 20:45:48

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:45:53', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '598bffa9-657f-4f11-a573-261e2a9f441c'	System	14 Sep 2020 14:46:10
User entered 'None (0)'	System	14 Sep 2020 14:46:10

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:45:55', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '598bffa9-657f-4f11-a573-261e2a9f441c'	System	14 Sep 2020 14:46:10
User entered 'None (0)'	System	14 Sep 2020 14:46:10



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:45:57', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '598bffa9-657f-4f11-a573-261e2a9f441c'	System	14 Sep 2020 14:46:10
User entered 'None (0)'	System	14 Sep 2020 14:46:10

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:45:59', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '598bffa9-657f-4f11-a573-261e2a9f441c'	System	14 Sep 2020 14:46:10
User entered 'None (0)'	System	14 Sep 2020 14:46:10

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:46:01', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '598bffa9-657f-4f11-a573-261e2a9f441c'	System	14 Sep 2020 14:46:10
User entered 'None (0)'	System	14 Sep 2020 14:46:10

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:46:03', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '598bffa9-657f-4f11-a573-261e2a9f441c'	System	14 Sep 2020 14:46:10
User entered 'None (0)'	System	14 Sep 2020 14:46:10

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:46:05', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '598bffa9-657f-4f11-a573-261e2a9f441c'	System	14 Sep 2020 14:46:10
User entered 'No (N)'	System	14 Sep 2020 14:46:10

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:11:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T09:46:09', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '598bffa9-657f-4f11-a573-261e2a9f441c'	System	14 Sep 2020 14:46:10
User entered '14 Sep 2020 09:46'	System	14 Sep 2020 14:46:10

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '14 Sep 2020 09:30'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 14:15:03



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T20:00:04', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f7fc0bb7-9273-426a-95e6-0f5b965e3f48'	System	15 Sep 2020 01:00:36
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:00:36

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T20:00:08', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f7fc0bb7-9273-426a-95e6-0f5b965e3f48'	System	15 Sep 2020 01:00:36
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:00:36

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T20:00:14', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f7fc0bb7-9273-426a-95e6-0f5b965e3f48'	System	15 Sep 2020 01:00:36
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:00:36

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T20:00:17', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f7fc0bb7-9273-426a-95e6-0f5b965e3f48'	System	15 Sep 2020 01:00:36
User entered 'No interference with activity (1)'	System	15 Sep 2020 01:00:36

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T20:00:20', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f7fc0bb7-9273-426a-95e6-0f5b965e3f48'	System	15 Sep 2020 01:00:36
User entered 'None (0)'	System	15 Sep 2020 01:00:36

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T20:00:22', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f7fc0bb7-9273-426a-95e6-0f5b965e3f48'	System	15 Sep 2020 01:00:36
User entered 'None (0)'	System	15 Sep 2020 01:00:36

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T20:00:24', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f7fc0bb7-9273-426a-95e6-0f5b965e3f48'	System	15 Sep 2020 01:00:36
User entered 'No (N)'	System	15 Sep 2020 01:00:36



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:11:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-14T20:00:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f7fc0bb7-9273-426a-95e6-0f5b965e3f48'	System	15 Sep 2020 01:00:36
User entered '14 Sep 2020 20:00'	System	15 Sep 2020 01:00:36

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '14 Sep 2020 12:55'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 2'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:19', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '707adf3a-4aba-4830-bdbd-65f918f3807c'	System	15 Sep 2020 23:50:50
User entered 'No interference with activity (1)'	System	15 Sep 2020 23:50:50

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:22', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '707adf3a-4aba-4830-bdbd-65f918f3807c'	System	15 Sep 2020 23:50:50
User entered 'No interference with activity (1)'	System	15 Sep 2020 23:50:50

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '707adf3a-4aba-4830-bdbd-65f918f3807c'	System	15 Sep 2020 23:50:50
User entered 'No interference with activity (1)'	System	15 Sep 2020 23:50:50

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:31', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '707adf3a-4aba-4830-bdbd-65f918f3807c'	System	15 Sep 2020 23:50:50
User entered 'No interference with activity (1)'	System	15 Sep 2020 23:50:50



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:33', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '707adf3a-4aba-4830-bdbd-65f918f3807c'	System	15 Sep 2020 23:50:50
User entered 'None (0)'	System	15 Sep 2020 23:50:50

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:34', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '707adf3a-4aba-4830-bdbd-65f918f3807c'	System	15 Sep 2020 23:50:50
User entered 'None (0)'	System	15 Sep 2020 23:50:50

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:37', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '707adf3a-4aba-4830-bdbd-65f918f3807c'	System	15 Sep 2020 23:50:50
User entered 'No (N)'	System	15 Sep 2020 23:50:50

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-15T18:50:42', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '707adf3a-4aba-4830-bdbd-65f918f3807c'	System	15 Sep 2020 23:50:50
User entered '15 Sep 2020 18:50'	System	15 Sep 2020 23:50:50

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 3'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:44', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '71f66829-9768-41d7-bb51-30483adad9d1'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:46', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '71f66829-9768-41d7-bb51-30483adad9d1'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:47', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '71f66829-9768-41d7-bb51-30483adad9d1'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:49', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '71f66829-9768-41d7-bb51-30483adad9d1'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:50', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '71f66829-9768-41d7-bb51-30483adad9d1'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:52', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '71f66829-9768-41d7-bb51-30483adad9d1'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:54', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '71f66829-9768-41d7-bb51-30483adad9d1'	System	16 Sep 2020 22:23:04
User entered 'No (N)'	System	16 Sep 2020 22:23:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-16T17:22:58', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '71f66829-9768-41d7-bb51-30483adad9d1'	System	16 Sep 2020 22:23:04
User entered '16 Sep 2020 17:22'	System	16 Sep 2020 22:23:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 14:15:03



**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 4'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:47', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ab57047f-09dd-40af-964c-c522d2681a7b'	System	18 Sep 2020 02:20:04
User entered 'None (0)'	System	18 Sep 2020 02:20:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:49', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ab57047f-09dd-40af-964c-c522d2681a7b'	System	18 Sep 2020 02:20:04
User entered 'None (0)'	System	18 Sep 2020 02:20:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:50', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ab57047f-09dd-40af-964c-c522d2681a7b'	System	18 Sep 2020 02:20:04
User entered 'None (0)'	System	18 Sep 2020 02:20:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:52', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ab57047f-09dd-40af-964c-c522d2681a7b'	System	18 Sep 2020 02:20:04
User entered 'None (0)'	System	18 Sep 2020 02:20:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:53', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ab57047f-09dd-40af-964c-c522d2681a7b'	System	18 Sep 2020 02:20:04
User entered 'None (0)'	System	18 Sep 2020 02:20:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:55', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ab57047f-09dd-40af-964c-c522d2681a7b'	System	18 Sep 2020 02:20:04
User entered 'None (0)'	System	18 Sep 2020 02:20:04



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:19:57', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ab57047f-09dd-40af-964c-c522d2681a7b'	System	18 Sep 2020 02:20:04
User entered 'No (N)'	System	18 Sep 2020 02:20:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-17T21:20:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'ab57047f-09dd-40af-964c-c522d2681a7b'	System	18 Sep 2020 02:20:04
User entered '17 Sep 2020 21:20'	System	18 Sep 2020 02:20:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 5'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:43:05', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a2a0e01-b535-430b-94a5-c873466c0c60'	System	19 Sep 2020 05:43:24
User entered 'None (0)'	System	19 Sep 2020 05:43:24

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:43:07', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a2a0e01-b535-430b-94a5-c873466c0c60'	System	19 Sep 2020 05:43:24
User entered 'None (0)'	System	19 Sep 2020 05:43:24

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:43:09', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a2a0e01-b535-430b-94a5-c873466c0c60'	System	19 Sep 2020 05:43:24
User entered 'None (0)'	System	19 Sep 2020 05:43:24



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:43:10', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a2a0e01-b535-430b-94a5-c873466c0c60'	System	19 Sep 2020 05:43:24
User entered 'None (0)'	System	19 Sep 2020 05:43:24

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:43:11', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a2a0e01-b535-430b-94a5-c873466c0c60'	System	19 Sep 2020 05:43:24
User entered 'None (0)'	System	19 Sep 2020 05:43:24

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:43:13', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a2a0e01-b535-430b-94a5-c873466c0c60'	System	19 Sep 2020 05:43:24
User entered 'None (0)'	System	19 Sep 2020 05:43:24

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:43:17', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a2a0e01-b535-430b-94a5-c873466c0c60'	System	19 Sep 2020 05:43:24
User entered 'No (N)'	System	19 Sep 2020 05:43:24

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:11:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T00:43:20', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1a2a0e01-b535-430b-94a5-c873466c0c60'	System	19 Sep 2020 05:43:24
User entered '19 Sep 2020 00:43'	System	19 Sep 2020 05:43:24

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 6'	System	14 Sep 2020 14:15:03



**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '01a53be9-06e9-433d-960f-87d6f57b9163'	System	19 Sep 2020 17:22:56
User entered 'None (0)'	System	19 Sep 2020 17:22:56

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:40', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '01a53be9-06e9-433d-960f-87d6f57b9163'	System	19 Sep 2020 17:22:56
User entered 'None (0)'	System	19 Sep 2020 17:22:56

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:42', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '01a53be9-06e9-433d-960f-87d6f57b9163'	System	19 Sep 2020 17:22:56
User entered 'None (0)'	System	19 Sep 2020 17:22:56

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:43', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '01a53be9-06e9-433d-960f-87d6f57b9163'	System	19 Sep 2020 17:22:56
User entered 'None (0)'	System	19 Sep 2020 17:22:56

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:46', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '01a53be9-06e9-433d-960f-87d6f57b9163'	System	19 Sep 2020 17:22:56
User entered 'None (0)'	System	19 Sep 2020 17:22:56

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:48', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '01a53be9-06e9-433d-960f-87d6f57b9163'	System	19 Sep 2020 17:22:56
User entered 'None (0)'	System	19 Sep 2020 17:22:56

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:50', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '01a53be9-06e9-433d-960f-87d6f57b9163'	System	19 Sep 2020 17:22:56
User entered 'No (N)'	System	19 Sep 2020 17:22:56

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-19T12:22:53', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '01a53be9-06e9-433d-960f-87d6f57b9163'	System	19 Sep 2020 17:22:56
User entered '19 Sep 2020 12:22'	System	19 Sep 2020 17:22:56



**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	14 Sep 2020 14:15:03
User entered 'Day 7'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:46', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '890fdab5-b425-4439-b0ac-252b8288efcc'	System	20 Sep 2020 20:46:04
User entered 'None (0)'	System	20 Sep 2020 20:46:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:47', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '890fdab5-b425-4439-b0ac-252b8288efcc'	System	20 Sep 2020 20:46:04
User entered 'None (0)'	System	20 Sep 2020 20:46:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:49', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '890fdab5-b425-4439-b0ac-252b8288efcc'	System	20 Sep 2020 20:46:04
User entered 'None (0)'	System	20 Sep 2020 20:46:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:50', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '890fdab5-b425-4439-b0ac-252b8288efcc'	System	20 Sep 2020 20:46:04
User entered 'None (0)'	System	20 Sep 2020 20:46:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:52', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '890fdab5-b425-4439-b0ac-252b8288efcc'	System	20 Sep 2020 20:46:04
User entered 'None (0)'	System	20 Sep 2020 20:46:04



US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:53', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '890fdab5-b425-4439-b0ac-252b8288efcc'	System	20 Sep 2020 20:46:04
User entered 'None (0)'	System	20 Sep 2020 20:46:04

US3362166

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:11:40

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)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:45:55', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '890fdab5-b425-4439-b0ac-252b8288efcc'	System	20 Sep 2020 20:46:04
User entered 'No (N)'	System	20 Sep 2020 20:46:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-09-20T15:46:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '890fdab5-b425-4439-b0ac-252b8288efcc'	System	20 Sep 2020 20:46:04
User entered '20 Sep 2020 15:46'	System	20 Sep 2020 20:46:04

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:11:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 14:15:03

**US3362166**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:29:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:34:56

**US3362166**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:29:49
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:34:56

**US3362166**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:29:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Sep 2020 17:34:56



US3362166

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:29:49
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:34:56

**US3362166**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:35:01

**US3362166**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'I'	System	21 Sep 2020 17:35:01

**US3362166**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:09:50

**US3362166**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:11
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 17:09:50

US3362166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 17:09:50

US3362166

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:11
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 17:09:50

**US3362166**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 17:10:17



**US3362166**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'I'	System	28 Sep 2020 17:10:17

**US3362166**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:32:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 16:40:51

**US3362166**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:32:55
User entered '05 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 16:40:51

**US3362166**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:32:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 16:40:51

US3362166

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:32:55
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 16:40:51

**US3362166**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:33:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 16:40:40

**US3362166**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'I'	System	05 Oct 2020 16:40:40

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:33:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:01:09



**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:33:12
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:01:09

US3362166

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:33:12
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Oct 2020 18:01:09

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'VISIT3'	System	12 Oct 2020 18:01:09

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:36:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:36:44
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:36:43
User entered '07:40'	(b) (4), (b) (6)	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered '12 Oct 2020 07:40'	System	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:36:41
User entered '36.8' C	(b) (4), (b) (6)	12 Oct 2020 18:04:18



US3362166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:36:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:36:34
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:36:33
User entered '64'	(b) (4), (b) (6)	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'bpm'	System	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:36:31
User entered '18'	(b) (4), (b) (6)	12 Oct 2020 18:04:18

US3362166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'breaths/min'	System	12 Oct 2020 18:04:18

US3362166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:13:18
User closed query 'Source show pressure to be: 161mmHg' (Site from CRA).		05 Nov 2020 17:13:17
Query 'Source show pressure to be: 161mmHg' answered with 'chart updated ' (Site from CRA).		21 Oct 2020 21:14:21
User entered '161' reason for change: Data Entry Error		21 Oct 2020 21:14:13
User opened query 'Source show pressure to be: 161mmHg' (Site from CRA).		21 Oct 2020 20:36:28
User entered '151'		12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'mmHg'	System	12 Oct 2020 18:04:18



US3362166

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:37:01
User entered '83'	(b) (4), (b) (6)	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'mmHg'	System	12 Oct 2020 18:04:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:11:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:37:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:06:04

US3362166

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:11:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:37:32
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:06:04

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:37:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:06:18

US3362166

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:37:45
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:06:18



**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:37:45
User entered '08:02'	(b) (4), (b) (6)	12 Oct 2020 18:06:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered '12 Oct 2020 08:02'	System	12 Oct 2020 18:06:18

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 16:05:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:37:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:01:00

**US3362166**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered '1'	System	12 Oct 2020 18:01:00

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 64'	System	17 Aug 2020 14:30:55

US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-10-19T14:15:17', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9878a8ac-fc0e-4115-806c-917fc4dcb8ad'	System	19 Oct 2020 19:15:29
User entered 'No (N)'	System	19 Oct 2020 19:15:29

US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-10-19T14:15:20', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9878a8ac-fc0e-4115-806c-917fc4dcb8ad'	System	19 Oct 2020 19:15:29
User entered 'No (N)'	System	19 Oct 2020 19:15:29

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-10-19T14:15:26', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9878a8ac-fc0e-4115-806c-917fc4dcb8ad'	System	19 Oct 2020 19:15:29
User entered '19 Oct 2020 14:15:26'	System	19 Oct 2020 19:15:29



**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 71'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49
Data entry locked.	System	17 Aug 2020 14:30:55
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:54:49
Data entry locked.	System	17 Aug 2020 14:30:55
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 78'	System	17 Aug 2020 14:30:55

US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-11-01T17:55:52', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '2a1bdae8-32c9-4d30-a325-866f3a4d9e32'	System	01 Nov 2020 23:56:01
User entered 'No (N)'	System	01 Nov 2020 23:56:01



US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-11-01T17:55:56', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '2a1bdae8-32c9-4d30-a325-866f3a4d9e32'	System	01 Nov 2020 23:56:01
User entered 'No (N)'	System	01 Nov 2020 23:56:01

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-11-01T17:55:59', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '2a1bdae8-32c9-4d30-a325-866f3a4d9e32'	System	01 Nov 2020 23:56:01
User entered '01 Nov 2020 17:55:59'	System	01 Nov 2020 23:56:01

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered 'Day 92'	System	17 Aug 2020 14:30:55

US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-11-14T09:55:03', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f843c83c-467f-478c-a96c-7683929f0f2b'	System	14 Nov 2020 15:55:15
User entered 'No (N)'	System	14 Nov 2020 15:55:15

US3362166

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:11:40

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-11-14T09:55:06', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f843c83c-467f-478c-a96c-7683929f0f2b'	System	14 Nov 2020 15:55:15
User entered 'No (N)'	System	14 Nov 2020 15:55:15

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-11-14T09:55:13', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f843c83c-467f-478c-a96c-7683929f0f2b'	System	14 Nov 2020 15:55:15
User entered '14 Nov 2020 09:55:13'	System	14 Nov 2020 15:55:15



**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:38:12
Data entry locked.	System	17 Aug 2020 14:30:55
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 14:30:55

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2020-11-19T18:57:25', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f4f5def0-69c0-4fe2-a6ff-8ab7c15352c5'	System	20 Nov 2020 00:57:39
User entered 'No (N)'	System	20 Nov 2020 00:57:39

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2020-11-19T18:57:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f4f5def0-69c0-4fe2-a6ff-8ab7c15352c5'	System	20 Nov 2020 00:57:39
User entered 'No (N)'	System	20 Nov 2020 00:57:39

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-11-19T18:57:36', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f4f5def0-69c0-4fe2-a6ff-8ab7c15352c5'	System	20 Nov 2020 00:57:39
User entered '19 Nov 2020 18:57:36'	System	20 Nov 2020 00:57:39

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2020-11-25T00:02:54', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'de2c6206-82b7-4e09-8ef8-ea08cb38075b'	System	25 Nov 2020 06:04:17
User entered 'Yes (Y)'	System	25 Nov 2020 06:04:17

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2020-11-25T00:03:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'de2c6206-82b7-4e09-8ef8-ea08cb38075b'	System	25 Nov 2020 06:04:17
User entered 'No (N)'	System	25 Nov 2020 06:04:17

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2020-11-25T00:03:04', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'de2c6206-82b7-4e09-8ef8-ea08cb38075b'	System	25 Nov 2020 06:04:17
User entered 'No (N)'	System	25 Nov 2020 06:04:17

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2020-11-25T00:03:27', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'de2c6206-82b7-4e09-8ef8-ea08cb38075b'	System	25 Nov 2020 06:04:17
User entered 'Yes (Y)'	System	25 Nov 2020 06:04:17

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Please 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 (92ac0576aaab068c)', Time: '2020-11-25T00:03:38', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'de2c6206-82b7-4e09-8ef8-ea08cb38075b'	System	25 Nov 2020 06:04:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 06:04:17

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-11-25T00:04:05', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'de2c6206-82b7-4e09-8ef8-ea08cb38075b'	System	25 Nov 2020 06:04:17
User entered '25 Nov 2020 00:04:05'	System	25 Nov 2020 06:04:17

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2020-12-02T15:09:14', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e562daa3-7790-4699-9e61-888c6de44db7'	System	02 Dec 2020 21:09:30
User entered 'No (N)'	System	02 Dec 2020 21:09:30

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2020-12-02T15:09:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e562daa3-7790-4699-9e61-888c6de44db7'	System	02 Dec 2020 21:09:30
User entered 'No (N)'	System	02 Dec 2020 21:09:30

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-12-02T15:09:25', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e562daa3-7790-4699-9e61-888c6de44db7'	System	02 Dec 2020 21:09:30
User entered '02 Dec 2020 15:09:25'	System	02 Dec 2020 21:09:30

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2020-12-09T00:48:05', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'be3271dd-095b-4253-8d84-3b820c002544'	System	09 Dec 2020 06:48:30
User entered 'No (N)'	System	09 Dec 2020 06:48:30

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2020-12-09T00:48:12', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'be3271dd-095b-4253-8d84-3b820c002544'	System	09 Dec 2020 06:48:30
User entered 'No (N)'	System	09 Dec 2020 06:48:30

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-12-09T00:48:26', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'be3271dd-095b-4253-8d84-3b820c002544'	System	09 Dec 2020 06:48:30
User entered '09 Dec 2020 00:48:26'	System	09 Dec 2020 06:48:30

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2020-12-16T00:02:24', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '32758407-557f-45ec-9cf3-74c518562c7f'	System	16 Dec 2020 06:02:40
User entered 'No (N)'	System	16 Dec 2020 06:02:40

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2020-12-16T00:02:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '32758407-557f-45ec-9cf3-74c518562c7f'	System	16 Dec 2020 06:02:40
User entered 'No (N)'	System	16 Dec 2020 06:02:40



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-12-16T00:02:33', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '32758407-557f-45ec-9cf3-74c518562c7f'	System	16 Dec 2020 06:02:40
User entered '16 Dec 2020 00:02:33'	System	16 Dec 2020 06:02:40

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2020-12-23T00:26:44', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1d2ea1ea-152a-4746-8aa4-9a3958ee54fa' User entered 'No (N)'	System	23 Dec 2020 06:26:56

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2020-12-23T00:26:47', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1d2ea1ea-152a-4746-8aa4-9a3958ee54fa'	System	23 Dec 2020 06:26:56
User entered 'No (N)'	System	23 Dec 2020 06:26:56

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-12-23T00:26:53', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1d2ea1ea-152a-4746-8aa4-9a3958ee54fa' User entered '23 Dec 2020 00:26:53'	System	23 Dec 2020 06:26:56
	System	23 Dec 2020 06:26:56

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2020-12-30T01:15:52', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '3af33265-59ee-41e8-87a2-fcb32e7c48c2'	System	30 Dec 2020 07:16:05
User entered 'No (N)'	System	30 Dec 2020 07:16:05

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2020-12-30T01:15:55', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '3af33265-59ee-41e8-87a2-fcb32e7c48c2'	System	30 Dec 2020 07:16:05
User entered 'No (N)'	System	30 Dec 2020 07:16:05

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2020-12-30T01:16:02', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '3af33265-59ee-41e8-87a2-fcb32e7c48c2'	System	30 Dec 2020 07:16:05
User entered '30 Dec 2020 01:16:02'	System	30 Dec 2020 07:16:05

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-01-06T01:07:39', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'fafc7393-62d1-40a5-aa2f-8a9ffd1e82d8'	System	06 Jan 2021 07:07:51
User entered 'No (N)'	System	06 Jan 2021 07:07:51

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-01-06T01:07:42', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'fafc7393-62d1-40a5-aa2f-8a9ffd1e82d8'	System	06 Jan 2021 07:07:51
User entered 'No (N)'	System	06 Jan 2021 07:07:51

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-01-06T01:07:48', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'fafc7393-62d1-40a5-aa2f-8a9ffd1e82d8'	System	06 Jan 2021 07:07:51
User entered '06 Jan 2021 01:07:48'	System	06 Jan 2021 07:07:51

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-01-13T00:13:17', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '071b9680-220e-4550-9e16-99d1d6c7666c'	System	13 Jan 2021 06:13:30
User entered 'No (N)'	System	13 Jan 2021 06:13:30

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-01-13T00:13:22', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '071b9680-220e-4550-9e16-99d1d6c7666c'	System	13 Jan 2021 06:13:30
User entered 'No (N)'	System	13 Jan 2021 06:13:30



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-01-13T00:13:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '071b9680-220e-4550-9e16-99d1d6c7666c'	System	13 Jan 2021 06:13:30
User entered '13 Jan 2021 00:13:28'	System	13 Jan 2021 06:13:30

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-01-20T00:02:28', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'aedd348e-85e4-43b7-9284-a74e09fea7b3'	System	20 Jan 2021 06:02:38
User entered 'No (N)'	System	20 Jan 2021 06:02:38

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-01-20T00:02:30', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'aedd348e-85e4-43b7-9284-a74e09fea7b3'	System	20 Jan 2021 06:02:38
User entered 'No (N)'	System	20 Jan 2021 06:02:38

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-01-20T00:02:35', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'aedd348e-85e4-43b7-9284-a74e09fea7b3' User entered '20 Jan 2021 00:02:35'	System	20 Jan 2021 06:02:38
	System	20 Jan 2021 06:02:38

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-01-27T00:15:25', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '14f34dc8-24a9-4706-8f5b-7c2172f578e1'	System	27 Jan 2021 06:15:38
User entered 'No (N)'	System	27 Jan 2021 06:15:38

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-01-27T00:15:29', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '14f34dc8-24a9-4706-8f5b-7c2172f578e1'	System	27 Jan 2021 06:15:38
User entered 'No (N)'	System	27 Jan 2021 06:15:38

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-01-27T00:15:35', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '14f34dc8-24a9-4706-8f5b-7c2172f578e1' User entered '27 Jan 2021 00:15:35'	System	27 Jan 2021 06:15:38
	System	27 Jan 2021 06:15:38

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-02-03T03:33:10', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e75132a1-7d5a-499e-b363-2ddeaf01db7'	System	03 Feb 2021 09:33:22
User entered 'No (N)'	System	03 Feb 2021 09:33:22

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-02-03T03:33:13', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e75132a1-7d5a-499e-b363-2ddeaf01db7'	System	03 Feb 2021 09:33:22
User entered 'No (N)'	System	03 Feb 2021 09:33:22

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-02-03T03:33:21', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'e75132a1-7d5a-499e-b363-2ddeaf01db7'	System	03 Feb 2021 09:33:22
User entered '03 Feb 2021 03:33:21'	System	03 Feb 2021 09:33:22

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-02-10T06:45:32', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6e224d47-243a-4ce5-a19f-74d4d7aa5c60'	System	10 Feb 2021 12:45:46
User entered 'No (N)'	System	10 Feb 2021 12:45:46

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-02-10T06:45:35', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6e224d47-243a-4ce5-a19f-74d4d7aa5c60'	System	10 Feb 2021 12:45:46
User entered 'No (N)'	System	10 Feb 2021 12:45:46



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-02-10T06:45:42', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6e224d47-243a-4ce5-a19f-74d4d7aa5c60'	System	10 Feb 2021 12:45:46
User entered '10 Feb 2021 06:45:42'	System	10 Feb 2021 12:45:46

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-02-17T02:51:32', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '89c64719-4cde-43c2-afd9-9dbc8ebb4db4'	System	17 Feb 2021 08:51:49
User entered 'No (N)'	System	17 Feb 2021 08:51:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-02-17T02:51:37', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '89c64719-4cde-43c2-afd9-9dbc8ebb4db4'	System	17 Feb 2021 08:51:49
User entered 'No (N)'	System	17 Feb 2021 08:51:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-02-17T02:51:45', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '89c64719-4cde-43c2-afd9-9dbc8ebb4db4'	System	17 Feb 2021 08:51:49
User entered '17 Feb 2021 02:51:45'	System	17 Feb 2021 08:51:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-02-24T01:05:07-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1520bd54-c658-494c-aade-3db8f08d3b8f' User entered 'No (N)'	System	24 Feb 2021 07:05:18
	System	24 Feb 2021 07:05:18

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-02-24T01:05:11-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1520bd54-c658-494c-aade-3db8f08d3b8f'	System	24 Feb 2021 07:05:18
User entered 'No (N)'	System	24 Feb 2021 07:05:18

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-02-24T01:05:16-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1520bd54-c658-494c-aade-3db8f08d3b8f' User entered '24 Feb 2021 01:05:16'	System	24 Feb 2021 07:05:18
	System	24 Feb 2021 07:05:18

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-03-04T04:36:25-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'cf588ccf-1f8e-454b-9f19-b26efc63cc05'	System	04 Mar 2021 10:36:37
User entered 'No (N)'	System	04 Mar 2021 10:36:37

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-03-04T04:36:28-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'cf588ccf-1f8e-454b-9f19-b26efc63cc05'	System	04 Mar 2021 10:36:37
User entered 'No (N)'	System	04 Mar 2021 10:36:37

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-03-04T04:36:33-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'cf588ccf-1f8e-454b-9f19-b26efc63cc05'	System	04 Mar 2021 10:36:37
User entered '04 Mar 2021 04:36:33'	System	04 Mar 2021 10:36:37

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-03-10T03:08:23-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f28d9780-c0e1-4bd1-affc-7ac895660bc6'	System	10 Mar 2021 09:08:36
User entered 'No (N)'	System	10 Mar 2021 09:08:36

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-03-10T03:08:25-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f28d9780-c0e1-4bd1-affc-7ac895660bc6'	System	10 Mar 2021 09:08:36
User entered 'No (N)'	System	10 Mar 2021 09:08:36



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-03-10T03:08:31-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'f28d9780-c0e1-4bd1-affc-7ac895660bc6' User entered '10 Mar 2021 03:08:31'	System	10 Mar 2021 09:08:36
	System	10 Mar 2021 09:08:36

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-03-17T05:19:51-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'a37e33d8-f057-4df0-8704-3babb3a22dae'	System	17 Mar 2021 10:20:06
User entered 'No (N)'	System	17 Mar 2021 10:20:06

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-03-17T05:19:54-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'a37e33d8-f057-4df0-8704-3babb3a22dae'	System	17 Mar 2021 10:20:06
User entered 'No (N)'	System	17 Mar 2021 10:20:06

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-03-17T05:20:00-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'a37e33d8-f057-4df0-8704-3babb3a22dae'	System	17 Mar 2021 10:20:06
User entered '17 Mar 2021 05:20:00'	System	17 Mar 2021 10:20:06

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-03-24T00:36:36-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '56ceca30-c982-4e23-b9e4-1e519819e567'	System	24 Mar 2021 05:36:51
User entered 'No (N)'	System	24 Mar 2021 05:36:51

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-03-24T00:36:42-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '56ceca30-c982-4e23-b9e4-1e519819e567'	System	24 Mar 2021 05:36:51
User entered 'No (N)'	System	24 Mar 2021 05:36:51

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-03-24T00:36:49-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '56ceca30-c982-4e23-b9e4-1e519819e567' User entered '24 Mar 2021 00:36:49'	System	24 Mar 2021 05:36:51
	System	24 Mar 2021 05:36:51

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-04-04T02:21:49-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'deb643d1-0ba1-43ee-b798-64143e02f142'	System	04 Apr 2021 07:22:00
User entered 'No (N)'	System	04 Apr 2021 07:22:00

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-04-04T02:21:52-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'deb643d1-0ba1-43ee-b798-64143e02f142'	System	04 Apr 2021 07:22:00
User entered 'No (N)'	System	04 Apr 2021 07:22:00

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-04-04T02:21:57-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'deb643d1-0ba1-43ee-b798-64143e02f142'	System	04 Apr 2021 07:22:00
User entered '04 Apr 2021 02:21:57'	System	04 Apr 2021 07:22:00

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-04-07T00:43:13-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9b87dbb5-dac3-407d-b582-071efb287bc4'	System	07 Apr 2021 05:43:24
User entered 'No (N)'	System	07 Apr 2021 05:43:24

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-04-07T00:43:17-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9b87dbb5-dac3-407d-b582-071efb287bc4'	System	07 Apr 2021 05:43:24
User entered 'No (N)'	System	07 Apr 2021 05:43:24



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-04-07T00:43:21-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '9b87dbb5-dac3-407d-b582-071efb287bc4'	System	07 Apr 2021 05:43:24
User entered '07 Apr 2021 00:43:21'	System	07 Apr 2021 05:43:24

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-04-14T01:34:43-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1323d95d-5eed-42e3-83e4-695504380eda' User entered 'No (N)'	System	14 Apr 2021 06:34:51
	System	14 Apr 2021 06:34:51

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-04-14T01:34:46-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1323d95d-5eed-42e3-83e4-695504380eda' User entered 'No (N)'	System	14 Apr 2021 06:34:51

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-04-14T01:34:50-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '1323d95d-5eed-42e3-83e4-695504380eda' User entered '14 Apr 2021 01:34:50'	System	14 Apr 2021 06:34:51
	System	14 Apr 2021 06:34:51

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-04-21T16:38:50-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'fa5b0395-0df4-4e5f-9b99-bcf76ec8e196'	System	21 Apr 2021 21:39:05
User entered 'No (N)'	System	21 Apr 2021 21:39:05

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-04-21T16:38:52-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'fa5b0395-0df4-4e5f-9b99-bcf76ec8e196'	System	21 Apr 2021 21:39:05
User entered 'No (N)'	System	21 Apr 2021 21:39:05

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-04-21T16:38:59-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'fa5b0395-0df4-4e5f-9b99-bcf76ec8e196'	System	21 Apr 2021 21:39:05
User entered '21 Apr 2021 16:38:59'	System	21 Apr 2021 21:39:05

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[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 (92ac0576aaab068c)', Time: '2021-04-28T01:37:42-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6aa257b5-f4e8-4e14-9925-a85907174316' User entered 'No (N)'	System	28 Apr 2021 23:31:52
	System	28 Apr 2021 23:31:52

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

Have you been exposed to someone with 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 (92ac0576aaab068c)', Time: '2021-04-28T01:37:44-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6aa257b5-f4e8-4e14-9925-a85907174316' User entered 'No (N)'	System	28 Apr 2021 23:31:52
	System	28 Apr 2021 23:31:52

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-04-28T01:37:48-05:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: '6aa257b5-f4e8-4e14-9925-a85907174316' User entered '28 Apr 2021 01:37:48'	System	28 Apr 2021 23:31:52
	System	28 Apr 2021 23:31:52

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 08:54:49



**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 08:54:49

**US3362166**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:11:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:54:49
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 08:54:49

US3362166

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:11:40**

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)	24 Apr 2021 10:57:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-03-01T19:25:06-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'b7f5fe43-adac-4487-bb19-866f6cadb23c'	System	02 Mar 2021 01:25:12
User entered 'No (N)'	System	02 Mar 2021 01:25:12

**US3362166**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:57:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92ac0576aaab068c)', Time: '2021-03-01T19:25:09-06:00', User OID: 'PatientReportedOutcome (US3362166)', ODM File OID: 'b7f5fe43-adac-4487-bb19-866f6cadb23c'	System	02 Mar 2021 01:25:12
User entered '01 Mar 2021 19:25:09'	System	02 Mar 2021 01:25:12

**US3362166**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:02:10
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:22:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:33:38

**US3362166**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:02:10
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:22:56
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:33:38



**US3362166**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:02:10
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:22:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:33:38

US3362166

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:02:10
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:22:56
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:33:38

**US3362166**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:02:31
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:22:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:33:44

**US3362166**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 10:14:45
User entered 'I'	System	06 Nov 2020 14:33:44

**US3362166**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:03:23
User entered 'Yes (Y)'	Alexandra Caillouet	11 Dec 2020 16:14:25
	(b) (4)	

**US3362166**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:03:23
User entered '11 Dec 2020'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:14:25

**US3362166**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:03:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Dec 2020 16:14:25
	Alexandra Caillouet	
	(b) (4)	

**US3362166**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:03:23
User entered empty.	(b) (4), (b) (6)	
	Alexandra Caillouet	11 Dec 2020 16:14:25
	(b) (4)	



**US3362166**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:03:28
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:14:30

**US3362166**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User entered 'I'	System	11 Dec 2020 16:14:30

**US3362166**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:13:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 20:35:17

**US3362166**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:13:18
User entered '11 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 20:35:17

**US3362166**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:13:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 20:35:17

US3362166

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:13:18
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 20:35:17

**US3362166**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:14:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 20:35:34

**US3362166**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User entered 'I'	System	11 Jan 2021 20:35:34



**US3362166**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 17:00:42

**US3362166**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:26
User entered '8 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 17:00:42

**US3362166**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Feb 2021 17:00:42

US3362166

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:11:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:26
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 17:00:42

**US3362166**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 17:00:47

**US3362166**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:47:41
User entered 'I'	System	08 Feb 2021 17:00:47

**US3362166**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:04:47
User entered 'Yes (Y)'	Alexandra Caillouet	01 Mar 2021 21:33:07
	(b) (4)	

**US3362166**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:47
User entered '1 Mar 2021'	Alexandra Caillouet (b) (4)	01 Mar 2021 21:33:07



US3362166

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:04:47
User entered 'Clinic (Clinic)'	Alexandra Caillouet	01 Mar 2021 21:33:07
	(b) (4)	

**US3362166**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User entered 'VISIT4'	System	01 Mar 2021 21:33:07

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered 'No (N)'	Alexandra Caillouet	30 Mar 2021 18:55:50
	(b) (4)	

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	System	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:55:50



US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	Alexandra Caillouet	30 Mar 2021 18:55:50
	(b) (4)	

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	System	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	Alexandra Caillouet	30 Mar 2021 18:55:50
	(b) (4)	

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	System	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	System	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:43:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	Alexandra Caillouet (b) (4)	30 Mar 2021 18:55:50



US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13
User entered empty.	System	30 Mar 2021 18:55:50

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13

US3362166

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	13 Apr 2021 17:41:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:35:13

**US3362166**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:11:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User entered 'No (N)'	Alexandra Caillouet	01 Mar 2021 21:34:45
	(b) (4)	

**US3362166**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:11:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User entered empty.	Alexandra Caillouet (b) (4)	01 Mar 2021 21:34:45

US3362166

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:05:08
User entered 'Yes (Y)'	Alexandra Caillouet	01 Mar 2021 21:35:04
	(b) (4)	

**US3362166**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:08
User entered '1 Mar 2021'	Alexandra Caillouet (b) (4)	01 Mar 2021 21:35:04

**US3362166**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:08
User entered '14:40'	Alexandra Caillouet (b) (4)	01 Mar 2021 21:35:04



**US3362166**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User entered '1 Mar 2021 14:40'	System	01 Mar 2021 21:35:04

US3362166

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:11:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:05:16
User entered 'Yes (Y)'	Alexandra Caillouet	01 Mar 2021 21:35:10
	(b) (4)	

**US3362166**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:42:40
User entered 'I'	System	01 Mar 2021 21:35:10

**US3362166**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 14:52:41

**US3362166**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:37
User entered '12 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 14:52:41

**US3362166**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Apr 2021 14:52:41

**US3362166**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:11:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	12 Apr 2021 20:35:37
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 14:52:41
	(b) (4), (b) (6)	

**US3362166**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 20:35:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 14:52:45



**US3362166**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 14:52:45

**US3362166**

**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:05:31
User entered '1 Dec 2020'	Alexandra Caillouet	01 Dec 2020 19:02:16
	(b) (4)	

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:11:40

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:05:31
User entered '11:05'	(b) (4), (b) (6)	
	Alexandra Caillouet	01 Dec 2020 19:02:16
	(b) (4)	

**US3362166**

**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:11:40**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:29
User entered '1 Dec 2020 11:05'	System	01 Dec 2020 19:02:16

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:11:40

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:05:31
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:02:16

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:11:40

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:31
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:02:16

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
User entered 'Day 1 (Day 1)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

**US3362166**

**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '28 Nov 2020'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54



US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User closed query 'Per CDM: It appears Assessment Not Done is checked but data is present. Please review Lines 1-3 and update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 12:29:26
Query 'Per CDM: It appears Assessment Not Done is checked but data is present. Please review Lines 1-3 and update accordingly.' answered with 'updated lines 1-3' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 19:07:16
User entered '0' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	08 Jan 2021 19:04:24
User opened query 'Per CDM: It appears Assessment Not Done is checked but data is present. Please review Lines 1-3 and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:30:49
User entered '1'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User closed query 'Per CDM re-query: It appears that "O2 Saturation" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:39:37
Query 'Per CDM re-query: It appears that "O2 Saturation" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	18 Jan 2021 23:37:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	18 Jan 2021 23:37:30
User opened query 'Per CDM re-query: It appears that "O2 Saturation" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 12:29:46
User closed query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1-3. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 12:29:46
Query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1-3. If not collected, please consider recording these as NOT DONE' answered with 'the ND 'Not Done' entry does not work for this field. ' (Site from DM).	Amy Thomassie (b) (4)	08 Jan 2021 19:08:18
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:08:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:04:24
User opened query 'Per CDM: It appears that both O2 Saturation and Temperature are not recorded for Days 1-3. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:31:00
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User entered '%'	System	18 Jan 2021 23:37:30
User entered empty.	System	08 Jan 2021 19:08:09
User entered '%'	System	08 Jan 2021 19:04:24
User entered empty.	System	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:04:24
User entered empty.	(b) (4)	
	Alexandra Caillouet	01 Dec 2020 19:03:54
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet	01 Dec 2020 19:03:54
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	Alexandra Caillouet	01 Dec 2020 19:03:54
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet	01 Dec 2020 19:03:54
	(b) (4)	

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet	01 Dec 2020 19:03:54
	(b) (4)	



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet	01 Dec 2020 19:03:54
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54



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**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: Symptom Log (1)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet	01 Dec 2020 19:03:54
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:11:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:03:54

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
User entered 'Day 2 (Day 2)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:06:44
User entered '29 Nov 2020'	Alexandra Caillouet	01 Dec 2020 19:04:45
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'I'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User closed query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:40:04
Query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	18 Jan 2021 23:38:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	18 Jan 2021 23:38:07
User opened query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 12:30:07
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45



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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User entered '%'	System	18 Jan 2021 23:38:07
User entered empty.	System	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:06:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 23:38:07
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:04:45
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	(b) (4) Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45



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Form: Symptom Log (2)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:11:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:05:46
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:04:45

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
User entered 'Day 3 (Day 3)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '30 Nov 2020'	Alexandra Caillouet	01 Dec 2020 19:05:28
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'l'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User closed query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 14:40:11
Query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	18 Jan 2021 23:38:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Alexandra Caillouet (b) (4)	18 Jan 2021 23:38:31
User opened query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 12:30:12
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User entered '%'	System	18 Jan 2021 23:38:31
User entered empty.	System	01 Dec 2020 19:05:28

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:06:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Jan 2021 23:38:31
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:05:28
	(b) (4)	



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	(b) (4) Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	(b) (4) Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	(b) (4) Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	(b) (4) Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:11:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	08 Jan 2021 19:06:51
User entered 'Not Done (Not Done)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:05:28



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
User entered 'Day 4 (Day 4)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:07:22

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:06:44
User entered '1 Dec 2020'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '0'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:07:22

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '99'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User entered '%'	System	01 Dec 2020 19:07:22

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '37.0' C	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:11:40**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	01 Dec 2020 19:07:22
	Alexandra Caillouet	
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:11:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Alexandra Caillouet	01 Dec 2020 19:07:22
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:18:35

**US3362166**

**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 18:18:35



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '0'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '98'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

**US3362166**

**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:11:40**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User entered '%'	System	02 Dec 2020 18:18:35

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '98.1' F	(b) (4), (b) (6)	02 Dec 2020 18:18:35

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

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**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:11:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	02 Dec 2020 18:18:35

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '3 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '96'	(b) (4), (b) (6)	03 Dec 2020 15:47:36



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User entered '%'	System	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '97.9' F	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:06:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36



US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:11:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	(b) (4), (b) (6)	03 Dec 2020 15:47:36

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
User entered 'Day 7 (Day 7)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '04 Dec 2020'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '0'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '97'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User entered '%'	System	04 Dec 2020 17:17:33

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered '98.1' F	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33



US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'Mild (Mild)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33



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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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**Folder: Covid-19 Assessment 01 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:11:40

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:33
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:06:44
User entered 'None (None)'	Crystal Rowell (b) (4)	04 Dec 2020 17:17:33



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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:07:25
User entered '1 Dec 2020'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:08:00

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:07:25
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:08:00

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:07:25
User closed query 'Per CDM: Please update this field when data becomes available or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 05:04:29
Query 'Per CDM: Please update this field when data becomes available or comment accordingly. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	08 Dec 2020 17:46:16
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	08 Dec 2020 17:46:10
User opened query 'Per CDM: Please update this field when data becomes available or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 07:23:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 05:42:07
Query 'Data is required. Please complete.' answered with 'results pending ' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 19:43:13
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Dec 2020 19:08:00
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:08:00

US3362166

Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:07:25
User entered '1 Dec 2020'	Alexandra Caillouet	01 Dec 2020 19:08:00
	(b) (4)	

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:07:25
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:08:00

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:07:25
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:08:00

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

[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)	02 May 2021 08:10:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:07:25
User entered 'No (N)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:08:00

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:07:25
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:08:00



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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:07:25
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:08:00

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Folder: Covid-19 Assessment 01 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:11:40

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:38
User entered '0'	System	08 Dec 2020 17:46:10

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Folder: Covid-19 Assessment 01 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:11:40

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 08:10:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:07:31
User entered 'No (N)'	(b) (4), (b) (6)	01 Dec 2020 19:08:29
	Alexandra Caillouet	
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User accepted default value 'Day 3 (Day 3)'	Alexandra Caillouet (b) (4)	17 Dec 2020 16:04:50

**US3362166**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:10:05
User entered 'Yes (Y)'	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

**US3362166**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:10:05
User entered '7 Dec 2020'	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User accepted default value 'Day 5 (Day 5)'	Alexandra Caillouet (b) (4)	17 Dec 2020 16:04:50

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:11:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:10:05
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 16:05:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:05:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	17 Dec 2020 16:05:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Dec 2020 16:04:50
User entered empty.	System	17 Dec 2020 16:04:50
	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:10:05
User entered empty.	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User accepted default value 'Day 7 (Day 7)'	Alexandra Caillouet (b) (4)	17 Dec 2020 16:04:50

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:11:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:10:05
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 16:05:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:05:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	17 Dec 2020 16:05:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Dec 2020 16:04:50
User entered empty.	System	17 Dec 2020 16:04:50
	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:10:05
User entered empty.	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User accepted default value 'Day 9 (Day 9)'	Alexandra Caillouet (b) (4)	17 Dec 2020 16:04:50

US3362166

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:11:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:10:05
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 16:05:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:05:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	17 Dec 2020 16:05:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Dec 2020 16:04:50
User entered empty.	System	17 Dec 2020 16:04:50
	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

**US3362166**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:10:05
User entered empty.	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

**US3362166**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User accepted default value 'Day 14 (Day 14)'	Alexandra Caillouet (b) (4)	17 Dec 2020 16:04:50



US3362166

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:11:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:10:05
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 16:05:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:05:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	17 Dec 2020 16:05:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Dec 2020 16:04:50
User entered empty.	System	17 Dec 2020 16:04:50
	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

**US3362166**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:10:05
User entered empty.	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

**US3362166**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User accepted default value 'Day 21 (Day 21)'	Alexandra Caillouet (b) (4)	17 Dec 2020 16:04:50

US3362166

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:11:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:10:05
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 16:05:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:05:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	17 Dec 2020 16:05:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Dec 2020 16:04:50
User entered empty.	System	17 Dec 2020 16:04:50
	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

**US3362166**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:10:05
User entered empty.	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

**US3362166**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User accepted default value 'Day 28 (Day 28)'	Alexandra Caillouet (b) (4)	17 Dec 2020 16:04:50

US3362166

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:11:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	24 Mar 2021 20:10:05
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 16:05:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:05:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Alexandra Caillouet	17 Dec 2020 16:05:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Dec 2020 16:04:50
User entered empty.	System	17 Dec 2020 16:04:50
	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	

**US3362166**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:29
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:10:05
User entered empty.	Alexandra Caillouet	17 Dec 2020 16:04:50
	(b) (4)	



**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:07:46
User entered 'Yes (Y)'	Alexandra Caillouet	01 Dec 2020 19:00:16
	(b) (4)	

US3362166

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:07:46
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 08:52:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	17 Dec 2020 16:05:26
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:35:51
User entered '1 Dec 2020'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:00:16

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:42
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:07:46
User entered 'Clinic (Clinic)'	Alexandra Caillouet	01 Dec 2020 19:00:16
	(b) (4)	

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:42
User entered 'SICKD1'	System	01 Dec 2020 19:00:16

US3362166

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:36
User entered 'Yes (Y)'	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:36
User entered '1 Dec 2020'	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:36
User entered '11:11'	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User entered '1 Dec 2020 11:11'	System	01 Dec 2020 19:01:30



US3362166

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:36
User entered '174' cm	Alexandra Caillouet	01 Dec 2020 19:01:30
DataPoint set to visible.	(b) (4)	
	System	01 Dec 2020 19:00:16

US3362166

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:36
User entered '148.7' kg	Alexandra Caillouet	01 Dec 2020 19:01:30
DataPoint set to visible.	(b) (4)	
	System	01 Dec 2020 19:00:16

US3362166

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:36
User entered '37.0' C	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	

US3362166

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:36
User entered 'Oral (Oral)'	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:08:36
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	

US3362166

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:08:36
User entered '63'	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User entered 'bpm'	System	01 Dec 2020 19:01:30

US3362166

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '18'	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	



US3362166

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:11:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User entered 'breaths/min'	System	01 Dec 2020 19:01:30

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:36
User entered '161'	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User entered 'mmHg'	System	01 Dec 2020 19:01:30

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:36
User entered '87'	Alexandra Caillouet	01 Dec 2020 19:01:30
	(b) (4)	

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52
User entered 'mmHg'	System	01 Dec 2020 19:01:30

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:11:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:53:52

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:11:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:56:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:43
User entered 'Yes (Y)'	Alexandra Caillouet	01 Dec 2020 19:01:39
	(b) (4)	



**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:11:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:56:43
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:43
User entered '1 Dec 2020'	Alexandra Caillouet	01 Dec 2020 19:01:39
	(b) (4)	

US3362166

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:11:40

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:56:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:52
User entered 'Yes (Y)'	Alexandra Caillouet	01 Dec 2020 19:01:47
	(b) (4)	

**US3362166**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:11:40**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:56:51
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:08:52
User entered '1 Dec 2020'	Alexandra Caillouet	01 Dec 2020 19:01:47
	(b) (4)	

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:10:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 19:22:57

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:10:15
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 19:22:57

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:11:40

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:10:15
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Jan 2021 19:22:57

**US3362166**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:11:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 19:22:57

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:11:40

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:10:21
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 19:23:25



**US3362166**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:11:40**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:51:01

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:11:40

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:10:21
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4), (b) (6)	11 Jan 2021 17:48:26
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'participant did not receive randomization assignment at today's visit.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 19:23:49
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	08 Jan 2021 19:23:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 19:23:25

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:11:40

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:36:53
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 21:25:11
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:53:17
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 15:53:12
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:25:27
User entered 'AMENDMENT 5 (AMENDMENT 5)'	System	10 Mar 2021 16:55:28
WR# 5295537		
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:51:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:11:40

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:10:21
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 19:23:25

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:11:40

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:36:53
User closed query 'Per CDM: Per sponsor review, please provide Participant Randomization Assignment. ' (Site from DM).		31 Mar 2021 16:38:19
Query 'Per CDM: Per sponsor review, please provide Participant Randomization Assignment. ' answered with 'updated' (Site from DM).		30 Mar 2021 15:28:44
DataPoint Un-verified.		30 Mar 2021 15:28:27
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error		30 Mar 2021 15:28:27
User opened query 'Per CDM: Per sponsor review, please provide Participant Randomization Assignment. ' (Site from DM).		30 Mar 2021 15:01:38
DataPoint Verified.		24 Mar 2021 20:10:21
User entered empty.		08 Jan 2021 19:23:25

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:11:40

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:10:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 07:29:31
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	08 Jan 2021 19:23:25

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:11:40

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:10:21
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 07:29:31
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	08 Jan 2021 19:23:25

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:11:40

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:10:21
User entered 'No (N)'	(b) (4), (b) (6)	08 Jan 2021 19:23:25



**US3362166**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:11:40**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User entered empty.	System	08 Jan 2021 19:23:25

**US3362166**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:11:40**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User entered empty.	System	08 Jan 2021 19:23:25

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:11:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 19:24:57

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:11:13
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 19:24:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:11:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:11:13
User entered '07:35'	(b) (4), (b) (6)	08 Jan 2021 19:24:57

**US3362166**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:11:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User entered '8 Jan 2021 07:35'	System	08 Jan 2021 19:24:57

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:11:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 19:25:10

US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:11:44
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 19:25:10



US3362166

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:11:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:11:44
User entered '07:36'	(b) (4), (b) (6)	08 Jan 2021 19:25:10

**US3362166**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:11:40**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:49
User entered '8 Jan 2021 07:36'	System	08 Jan 2021 19:25:10

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:11:40**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:12:15
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	31 Aug 2020 20:23:31
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 14:27:05

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:11:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
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)	23 Oct 2020 21:10:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 21:10:43
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)	05 Sep 2020 19:19:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Sep 2020 19:19:41
Data point term sent to Coder	System	05 Sep 2020 19:18:45
User entered 'nausea'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 10:13:34
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'symptoms did not last more than 48 hours ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:21:16
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:39:35
User entered 'No (N)'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 19:17:47



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	16 Sep 2020 23:59:23
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	14 Sep 2020 14:15:03
User entered '24 Aug 2020'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
User entered empty.	System	05 Sep 2020 19:17:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 16:15:11
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 16:15:11
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:11:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
User entered empty.	System	05 Sep 2020 19:17:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

US3362166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'None (NONE)'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'I'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

US3362166

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 16:15:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:11:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:17:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
User entered '0'	System	05 Sep 2020 19:17:47

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55
User entered '0'	System	05 Sep 2020 19:17:47

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:58:55

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:11:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 10:13:56
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'UPDATED; SYMPTOMS DID NOT LAST MORE THAN 48 HOURS' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:41:33
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:39:45
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 19:20:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 19:20:42
Data point term sent to Coder	System	05 Sep 2020 19:19:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'diarrhea'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 19:18:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	16 Sep 2020 23:59:23
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	14 Sep 2020 14:15:03
User entered '24 Aug 2020'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
User entered empty.	System	05 Sep 2020 19:18:51



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 16:41:19
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 16:41:19
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:11:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
User entered empty.	System	05 Sep 2020 19:18:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

US3362166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

US3362166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	



**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

US3362166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'None (NONE)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'I'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

US3362166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

US3362166

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 16:41:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:11:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:18:51
	(b) (4)	

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
User entered '0'	System	05 Sep 2020 19:18:51

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00
User entered '0'	System	05 Sep 2020 19:18:51

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:00

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:11:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Tooth fracture, LLT: Tooth fracture - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 14:46:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 14:46:43
	(b) (4)	
Data point term sent to Coder	System	06 Oct 2020 14:44:46
User entered 'cracked tooth'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '30 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

US3362166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Oct 2020 14:45:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 14:45:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Oct 2020 14:45:41
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 14:45:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Oct 2020 14:44:21
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Oct 2020 14:44:21
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:11:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
User entered empty.	System	06 Oct 2020 14:45:56
User entered '30 Sep 2020 00:00'	System	06 Oct 2020 14:45:41
User entered '30 Sep 2020 UN:UN' (non-conformant).	System	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '1 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	06 Oct 2020 14:45:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 14:45:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Oct 2020 14:45:41
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 14:45:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Oct 2020 14:44:21
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	06 Oct 2020 14:44:21
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
User entered empty.	System	06 Oct 2020 14:45:56
User entered '1 Oct 2020 00:00'	System	06 Oct 2020 14:45:41
User entered '1 Oct 2020 UN:UN' (non-conformant).	System	06 Oct 2020 14:44:21



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

US3362166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

US3362166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
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	06 Oct 2020 14:45:41
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).		06 Oct 2020 14:45:41
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	06 Oct 2020 14:44:21
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 14:45:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

US3362166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User closed query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you.	(b) (4), (b) (6)	19 Nov 2020 11:40:55
' (Site from DM).		
Query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you.	(b) (4), (b) (6)	18 Nov 2020 20:21:40
' answered with 'updated' (Site from DM).		
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Nov 2020 20:21:33
reason for change: Data Entry Error		
User opened query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you.	(b) (4), (b) (6)	18 Nov 2020 07:59:28
' (Site from DM).		
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 14:44:21



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

US3362166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User closed query 'Per DM CLR: Treatment Required = 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) (4), (b) (6)	05 Nov 2020 05:31:41
Query 'Per DM CLR: Treatment Required = 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 'con procedure updated ' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	31 Oct 2020 14:19:16
User opened query 'Per DM CLR: Treatment Required = 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)	30 Oct 2020 03:41:15
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	06 Oct 2020 14:44:21

US3362166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:44:21

US3362166

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:11:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:44:21

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
User entered '0'	System	06 Oct 2020 14:44:21

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
User entered '0'	System	06 Oct 2020 14:44:21

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:05
User entered '0'	System	06 Oct 2020 14:44:21



**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:11:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 14:37:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 14:37:31
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 14:35:59
User entered 'Worsening Hypertension'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '14 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 14:35:57
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 14:35:57
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 14:35:34
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:35:34

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:11:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
User entered '14 Sep 2020 00:00'	System	13 Oct 2020 14:35:57
User entered empty.	System	13 Oct 2020 14:35:34



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 16:22:26
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	11 Dec 2020 16:22:26
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 16:22:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 16:22:44
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	11 Dec 2020 16:22:44
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	11 Dec 2020 16:22:18
User entered '7 Dec 2020' reason for change: Data Entry Error	Alexandra Caillouet	11 Dec 2020 16:22:18
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Dec 2020 15:41:20
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Alexandra Caillouet	11 Dec 2020 16:23:07
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Dec 2020 16:22:26
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:35:34

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:11:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
User entered empty.	System	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:35:34



US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:35:34



US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'l'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Alexandra Caillouet	11 Dec 2020 16:22:44
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Alexandra Caillouet	11 Dec 2020 16:22:18
Data Entry Error	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 14:35:34

US3362166

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:35:34



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:11:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:35:34

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
User entered '0'	System	13 Oct 2020 14:35:34

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11
User entered '0'	System	13 Oct 2020 14:35:34

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:11

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:11:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM). Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'COVID-19 Swab from 01 DEC 2020 was negative. The rest of the viral respiratory panel was also negative. Unknown causative organism.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 14:58:30
	Alexandra Caillouet (b) (4)	31 Dec 2020 17:35:04
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:46:41
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:24:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:24:53
Data point term sent to Coder	System	11 Dec 2020 16:24:06
Coding entries removed.	Alexandra Caillouet (b) (4)	11 Dec 2020 16:23:54
User entered 'Upper Respiratory Illness' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	11 Dec 2020 16:23:54
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:41:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:41:25
Data point term sent to Coder	System	01 Dec 2020 19:11:46
User entered 'Suspected COVID19'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:11:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'No (N)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:11:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '28 Nov 2020'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:11:36

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:11:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
User entered empty.	System	01 Dec 2020 19:11:36

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet	11 Dec 2020 16:23:54
	(b) (4)	
User entered 'Yes (Y)'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '7 Dec 2020' reason for change: Data Entry Error	Alexandra Caillouet	11 Dec 2020 16:23:54
	(b) (4)	
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:11:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
User entered empty.	System	01 Dec 2020 19:11:36



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'No (N)'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'l'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered '0'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Alexandra Caillouet	11 Dec 2020 16:23:54
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:11:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
	(b) (4)	
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:11:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
User entered '0'	System	01 Dec 2020 19:11:36

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16
User entered '0'	System	01 Dec 2020 19:11:36

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:16



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:11:40

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:03:43
Un-reviewed for Safety.		16 Dec 2020 15:03:36
Reviewed for Safety.		16 Dec 2020 14:59:57
User entered 'USA-US112-2020-mRNA-1273-P301000015'	System	11 Dec 2020 20:11:16
User entered 'New'	(b) (4), (b) (6)	11 Dec 2020 20:11:16

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:11:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User closed query 'Per DM CLR: Please confirm in response what has been updated. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 08:43:59
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 20:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Jan 2021 20:28:08
Query 'Per DM CLR: Please confirm in response what has been updated. Thank you!' answered with 'updated ' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	20 Jan 2021 20:13:07
Data point term sent to Coder	System	20 Jan 2021 20:12:37
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	20 Jan 2021 20:12:31
User entered 'Worsening of Diabetes Type 2' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	20 Jan 2021 20:12:31
User opened query 'Per DM CLR: Please confirm in response what has been updated. Thank you!' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 14:59:56
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of DIABETES TYPE II. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 14:59:56
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of DIABETES TYPE II. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:11:40

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of DIABETES TYPE II. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:36:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 16:30:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	11 Dec 2020 16:30:01
Data point term sent to Coder	System	11 Dec 2020 16:29:14
User entered 'Hyperglycemia'	Alexandra Caillouet	11 Dec 2020 16:28:33
	(b) (4)	

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'No (N)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'No (N)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered empty.	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33



**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'No (N)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '7 Dec 2020'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered empty.	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Grade 4 (Grade 4)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

US3362166

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:11:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33



**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'I'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '25 Nov 2020'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'No (N)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered empty.	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Not Applicable (NOT APPLICABLE)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'I'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered empty.	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:11:40

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User closed query 'Per CDM: Thank you for the response. Please note that ConProc section of the eCRF allows to record diagnostic procedures from the drop-down menu of 'Indication'. Please review and update as needed, else provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:41:24
Query 'Per CDM: Thank you for the response. Please note that ConProc section of the eCRF allows to record diagnostic procedures from the drop-down menu of 'Indication'. Please review and update as needed, else provide clarification.' answered with 'updated conproc' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	19 Feb 2021 18:28:42
User opened query 'Per CDM: Thank you for the response. Please note that ConProc section of the eCRF allows to record diagnostic procedures from the drop-down menu of 'Indication'. Please review and update as needed, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:34:37
User closed query 'Per DM CLR: Narrative = CHEMISTRY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:34:37
Query 'Per DM CLR: Narrative = CHEMISTRY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' answered with 'chemistry panel is a diagnostic test not a procedure' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	17 Feb 2021 17:17:59
User opened query 'Per DM CLR: Narrative = CHEMISTRY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 06:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:11:40

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if adverse events #6 and #7 are duplicate events of worsening of diabetes type 2. If so, please consider deleting one of the duplicate events. If no, please update the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 13:05:50
Query 'PV Query: Please confirm if adverse events #6 and #7 are duplicate events of worsening of diabetes type 2. If so, please consider deleting one of the duplicate events. If no, please update the event term accordingly.' answered with 'line 7 inactivated ' (Site from Safety).	Amy Thomassie (b) (4)	29 Jan 2021 20:13:23
User opened query 'PV Query: Please confirm if adverse events #6 and #7 are duplicate events of worsening of diabetes type 2. If so, please consider deleting one of the duplicate events. If no, please update the event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 15:26:05
User closed query 'Per DM CLR: SAE Narrative = CHEMISTRY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 07:42:23
User closed query 'Per DM CLR: SAE Narrative = HE DID HAVE ACUTE KIDNEY INJURY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 15:05:09
Query 'Per DM CLR: SAE Narrative = HE DID HAVE ACUTE KIDNEY INJURY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'AKI included as separate AE.' (Site from DM).	Alexandra Caillouet (b) (4)	19 Jan 2021 22:49:14
Query 'Per DM CLR: SAE Narrative = CHEMISTRY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'chemistry is not a procedure or surgery' (Site from DM).	Amy Thomassie (b) (4)	12 Jan 2021 21:18:22

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:11:40

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = HE DID HAVE ACUTE KIDNEY INJURY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:36:39
User opened query 'Per DM CLR: SAE Narrative = CHEMISTRY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 05:36:32
User closed query 'PV-Query: Kindly provide information on any identified triggers for the reported event to include poor adherence/non compliance, infections, medication, stress or dietary. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 15:17:23
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 15:17:22
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 15:17:20
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 15:17:18
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'this was emailed per query to Safety_Moderna@iqvia.com thank you ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 23:10:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:11:40

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'this was emailed today thank you ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 23:10:16
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'COVID-19 testing not done during hospital admission.' (Site from Safety).	Alexandra Caillouet (b) (4)	17 Dec 2020 21:53:40
Query ' PV-Query: Kindly provide information on any identified triggers for the reported event to include poor adherence/non compliance, infections, medication, stress or dietary. ' answered with 'Medication noncompliance' (Site from Safety).	Alexandra Caillouet (b) (4)	17 Dec 2020 21:45:05
User opened query ' PV-Query: Kindly provide information on any identified triggers for the reported event to include poor adherence/non compliance, infections, medication, stress or dietary. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 11:59:47
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 11:59:22
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 11:59:06
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 11:58:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Dec 2020 21:40:32
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Dec 2020 21:40:32

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:11:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'On 24 NOV 2020, the subject used a co-worker's glucometer to check his glucose. His blood glucose level at that time read as "high". Subject had reportedly stopped taking his insulin approximately 6 months prior after losing 50 lbs. Subject was admitted overnight after glucose on chemistry was noted to be 704. No anion gap or acidosis. He did have acute kidney injury. He was placed in observation for IV fluid resuscitation and insulin administration.' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	15 Dec 2020 21:40:32
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Dec 2020 16:28:33
User entered empty.	Alexandra Caillouet (b) (4)	11 Dec 2020 16:28:33

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Dec 2020 16:28:33

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Dec 2020 16:28:33



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Dec 2020 16:28:33

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:31:44
User entered 'USA-US112-2020-mRNA-1273-P301000015'	(b) (4), (b) (6)	20 Jan 2021 19:43:42

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:11:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 22:49:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 22:49:11
Data point term sent to Coder	System	19 Jan 2021 22:48:14
User entered 'Acute Kidney Injury'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'No (N)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'No (N)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered empty.	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01



**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 22:48:01

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Amy Thomassie (b) (4)	06 Mar 2021 20:26:24
User entered 'Yes (Y)'	(b) (4)	
	Alexandra Caillouet	19 Jan 2021 22:48:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
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)	08 Mar 2021 17:52:22
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.' answered with 'updated' (Site from Safety).	Amy Thomassie (b) (4)	06 Mar 2021 20:26:57
User entered '07 Dec 2020' reason for change: Data Entry Error	Amy Thomassie (b) (4)	06 Mar 2021 20:26:24
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)	25 Feb 2021 13:23:41
User entered empty.	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered empty.	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Grade 4 (Grade 4)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:11:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:08:14
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'con procedure # 3' (Site from DM).	Amy Thomassie (b) (4) (b) (4)	06 Mar 2021 20:28:13
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 13:37:34
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01



**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'I'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '25 Nov 2020'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'No (N)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered empty.	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Not Related (NOT RELATED)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'Not Applicable (NOT APPLICABLE)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:11:40

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:37:39
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:48
DataPoint Un-verified.	Crystal Rowell (b) (4)	25 Mar 2021 15:13:37
Signature has been broken.	Crystal Rowell (b) (4)	25 Mar 2021 15:13:37
User entered '0' reason for change: Data Entry Error	Crystal Rowell (b) (4)	25 Mar 2021 15:13:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '1' reason for change: Data Entry Error	Amy Thomassie (b) (4)	17 Feb 2021 17:19:09
User entered '0'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:37:39
User signature succeeded.	Jordan Whatley (b) (4)	27 Mar 2021 00:09:48
User closed query 'Per DM CLR - RQ: Site's response noted. However, if the same IV fluids were given for this AE, please update the CM indication to include this AE (if the CM is within the AE timeframe). Review and update as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 16:35:11
Query 'Per DM CLR - RQ: Site's response noted. However, if the same IV fluids were given for this AE, please update the CM indication to include this AE (if the CM is within the AE timeframe). Review and update as applicable. Otherwise, clarify. ' answered with 'updated ' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	25 Mar 2021 15:14:19
DataPoint Un-verified.	Crystal Rowell (b) (4) (b) (4)	25 Mar 2021 15:13:37
Signature has been broken.	Crystal Rowell (b) (4) (b) (4)	25 Mar 2021 15:13:37
User entered '1' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	25 Mar 2021 15:13:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User opened query 'Per DM CLR - RQ: Site's response noted. However, if the same IV fluids were given for this AE, please update the CM indication to include this AE (if the CM is within the AE timeframe). Review and update as applicable. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:56:59
User signature succeeded.	Jordan Whatley (b) (4) (b) (4)	13 Mar 2021 22:16:05
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)	18 Feb 2021 16:14:31

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:11:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
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 'TV fluids were given but are captures for AE of worsening diabetes ' (Site from DM).	Amy Thomassie (b) (4)	17 Feb 2021 17:20:09
User entered '0' reason for change: Data Entry Error	Amy Thomassie (b) (4)	17 Feb 2021 17:19:09
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)	16 Feb 2021 06:11:38
User entered '1'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered '0'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:11:40

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:52:29
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Amy Thomassie (b) (4) (b) (4)	06 Mar 2021 20:28:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Amy Thomassie (b) (4) (b) (4)	06 Mar 2021 20:26:24
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 13:23:48
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered empty.	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:15:02
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:16:05
User entered 'ON 24 NOV 2020, THE SUBJECT USED A CO-WORKER'S GLUCOMETER TO CHECK HIS GLUCOSE. HIS BLOOD GLUCOSE LEVEL AT THAT TIME READ AS "HIGH". SUBJECT HAD REPORTEDLY STOPPED TAKING HIS INSULIN APPROXIMATELY 6 MONTHS PRIOR AFTER LOSING 50 LBS. SUBJECT WAS ADMITTED OVERNIGHT AFTER GLUCOSE ON CHEMISTRY WAS NOTED TO BE 704. NO ANION GAP OR ACIDOSIS. HE DID HAVE ACUTE KIDNEY INJURY. HE WAS PLACED IN OBSERVATION FOR IV FLUID RESUSCITATION AND INSULIN ADMINISTRATION.'	Alexandra Caillouet (b) (4)	19 Jan 2021 22:48:01

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Jan 2021 22:48:01

**US3362166**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Jan 2021 22:48:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:11:40

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:16:15
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:10:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 21:04:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 21:04:58
	(b) (4)	
Data point term sent to Coder	System	09 Dec 2020 21:04:35
Coding entries removed.	Alexandra Caillouet	09 Dec 2020 21:04:28
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 16:31:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 16:31:23
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 16:30:48
Coding entries removed.	(b) (4), (b) (6)	05 Oct 2020 16:30:07
	(b) (4), (b) (6)	
User entered 'XARELTO' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 16:30:07
	(b) (4), (b) (6)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 11:41:54
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	08 Sep 2020 11:41:54
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	05 Sep 2020 19:12:41
User entered 'xerelto'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'HISTORY OF PULMONARY EMBOLUS/ Cardiac health and wellness' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	09 Dec 2020 21:04:28
User closed query 'Per CDM: Per previous query response "Updated"; however, the update is not reflecting in corresponding MH. Please verify and update accordingly ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:27:09
Query 'Per CDM: Per previous query response "Updated"; however, the update is not reflecting in corresponding MH. Please verify and update accordingly ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:14:05
User opened query 'Per CDM: Per previous query response "Updated"; however, the update is not reflecting in corresponding MH. Please verify and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 08:37:49
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding MH (2009). Please review and reconcile Con Med and MH start/stop dates as appropriate. Otherwise, please clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 08:36:34
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding MH (2009). Please review and reconcile Con Med and MH start/stop dates as appropriate. Otherwise, please clarify. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	09 Nov 2020 17:58:46
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding MH (2009). Please review and reconcile Con Med and MH start/stop dates as appropriate. Otherwise, please clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:58:45
User entered 'history of pulmonary embolus'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '20'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once daily (QD)'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Oral (ORAL)'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'UN UNK 2009' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:14:00
User entered 'UN UNK 2007' reason for change: Data Entry Error	Alexandra Caillouet	09 Nov 2020 17:58:33
	(b) (4)	
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2009). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:52:19
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2009). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'UPDATE' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:33:13
User entered 'UN UNK 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 16:31:37
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (2009). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 14:18:47
User entered 'un UNK 2007'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User closed query 'Per DM CLR: The corresponding Medical History has resolved, however the medication is still ongoing. Please verify and update stop dates for Medical History and/or medication as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 01:54:19
Query 'Per DM CLR: The corresponding Medical History has resolved, however the medication is still ongoing. Please verify and update stop dates for Medical History and/or medication as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'Initially started for History of PE, ongoing for use for cardiac health/wellness.' (Site from DM).	Alexandra Caillouet (b) (4)	09 Dec 2020 21:04:56
User opened query 'Per DM CLR: The corresponding Medical History has resolved, however the medication is still ongoing. Please verify and update stop dates for Medical History and/or medication as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 17:59:37
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:11:40
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:11:40



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:11:40

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 19:11:40

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 19:14:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 19:14:39
	(b) (4)	
Data point term sent to Coder	System	05 Sep 2020 19:13:41
User entered 'metoprolol'	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'hypertension'	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:40

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg. 25 mg, 50 mg, etc.) or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:51:49
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg. 25 mg, 50 mg, etc.) or provide explanation for alternate dosage.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 16:34:21
User entered '25' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 16:34:15
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg. 25 mg, 50 mg, etc.) or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 14:20:18
User entered '15'	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 19:13:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 19:13:26
User entered 'once daily (QD)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 19:13:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 19:13:09
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:11:40

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 19:13:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 19:13:26
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	05 Sep 2020 19:13:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 19:13:09
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'un Sep 1990'	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 19:13:09

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 19:13:09



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:13:09
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:13:26
User entered empty.	System	05 Sep 2020 19:13:09

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:13:26
User entered empty.	System	05 Sep 2020 19:13:09

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 19:13:26
User entered empty.	System	05 Sep 2020 19:13:09

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 19:15:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 19:15:40
	(b) (4)	
Data point term sent to Coder	System	05 Sep 2020 19:14:42
User entered 'pravastatin'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'hyperlipidemia'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '40'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once daily (QD)'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Oral (ORAL)'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'un UNK 2010'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:14:16
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:14:16

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:14:16

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 19:14:16

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 19:16:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 19:16:40
Data point term sent to Coder	System	05 Sep 2020 19:15:43
User entered 'lisinopril'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 19:15:06

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'hypertension'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '20'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once daily (QD)'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Oral (ORAL)'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:11:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'un UNK 1990'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:15:06
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:15:06

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 19:15:06

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 19:15:06



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 19:17:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 19:17:40
Data point term sent to Coder	System	05 Sep 2020 19:16:44
User entered 'lantus'	Amy Thomassie (b) (4) (b) (4)	05 Sep 2020 19:16:12

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'diabetes Type II'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '40' reason for change: Data Entry Error	Alexandra Caillouet	01 Dec 2020 19:18:56
	(b) (4)	
User entered '4'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Other (OTHER)'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'units'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'once daily (QD)'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'un UNK 2010'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet	10 Dec 2020 19:43:02
	(b) (4)	
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	24 Mar 2021 20:17:32
User entered 'un May 2020' reason for change: Data Entry Error	Alexandra Caillouet	10 Dec 2020 19:43:02
User entered empty.	(b) (4)	05 Sep 2020 19:16:12

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Amy Thomassie (b) (4)	05 Sep 2020 19:16:12

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User entered '1'	System	05 Sep 2020 19:16:12



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User entered '1'	System	05 Sep 2020 19:16:12

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:06
User entered '804 (804)'	System	05 Sep 2020 19:16:12

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:02:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:02:25
Data point term sent to Coder	System	06 Oct 2020 15:01:23
User entered 'hydrocodone/acetaminophen'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'tooth extraction/ tooth cracked'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '10-325 mg'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:00:37



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '01 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:00:37



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 15:00:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 15:00:37

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:36:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:36:39
Data point term sent to Coder	System	09 Nov 2020 18:00:42
Coding entries removed.	Alexandra Caillouet (b) (4)	09 Nov 2020 17:59:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:03:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:03:15
Data point term sent to Coder	System	06 Oct 2020 15:02:25
User entered 'amoxicillin'	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:02:01

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the treatment indication instead of the medical surgical procedure. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 09:52:47
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the treatment indication instead of the medical surgical procedure. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	09 Nov 2020 17:59:57
User entered 'Fractured tooth resulting in need for tooth extraction.' reason for change: Per Query Resolution	Alexandra Caillouet (b) (4)	09 Nov 2020 17:59:52
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the treatment indication instead of the medical surgical procedure. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:59:31
User entered 'tooth extraction'	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '500'	(b) (4), (b) (6)	06 Oct 2020 15:02:01



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'three times daily (TID)'	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '1 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 15:02:01



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)' reason for change: Data Entry Error		06 Nov 2020 14:26:49
User entered 'Yes (Y)'		06 Oct 2020 15:02:01

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '8 Oct 2020' reason for change: Data Entry Error		06 Nov 2020 14:26:49
User entered empty.		06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User entered '3'	System	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User entered '1'	System	06 Oct 2020 15:02:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:51
User entered '804 (804)'	System	06 Oct 2020 15:02:01

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 19:27:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 19:27:56
Data point term sent to Coder	System	01 Dec 2020 19:27:22
User entered 'Victoza'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:26:52

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	01 Dec 2020 19:26:52
	(b) (4)	



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Diabetes Mellitus Type II'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:26:52

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0.6'	Alexandra Caillouet	01 Dec 2020 19:26:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	Alexandra Caillouet	01 Dec 2020 19:26:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:26:52

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once daily (QD)'	Alexandra Caillouet	01 Dec 2020 19:26:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:26:52
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:26:52

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:26:52



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '25 Nov 2020'	Alexandra Caillouet	01 Dec 2020 19:26:52
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:26:52

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	01 Dec 2020 19:26:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '1 Dec 2020'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:26:52

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	01 Dec 2020 19:26:52
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User entered '1'	System	01 Dec 2020 19:26:52

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User entered '1'	System	01 Dec 2020 19:26:52

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:55
User entered '804 (804)'	System	01 Dec 2020 19:26:52



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 08:22:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 08:22:58
Data point term sent to Coder	System	01 Dec 2020 19:29:24
User entered 'Victoza'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:28:29

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Diabetes Mellitus'	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '1.2'	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once daily (QD)'	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:28:29



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	01 Dec 2020 19:28:29

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	01 Dec 2020 21:08:23
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 21:08:23
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	01 Dec 2020 19:28:29
User entered '02 Dec 2020'	Alexandra Caillouet (b) (4)	01 Dec 2020 19:28:29

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Yes (Y)'	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	01 Dec 2020 19:28:29
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 19:28:29



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 19:28:29

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 19:28:29

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
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: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:22:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 00:22:48
Data point term sent to Coder	System	10 Dec 2020 19:28:55
Data point term sent to Coder	System	10 Dec 2020 19:25:51
User entered 'Lactated Ringers Bolus'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:25:37

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:25:37
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hyperglycemia'	Alexandra Caillouet	10 Dec 2020 19:25:37
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '2000'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:25:37

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mL (mL)'	Alexandra Caillouet	10 Dec 2020 19:25:37
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:25:37



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once (ONCE)'	Alexandra Caillouet	10 Dec 2020 19:25:37
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:25:37
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)' reason for change: Data Entry Error	Alexandra Caillouet	10 Dec 2020 19:28:31
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet	10 Dec 2020 19:25:37
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:25:37

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:25:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:25:37

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:25:37

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:25:37



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:11:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:25:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User entered empty.	System	10 Dec 2020 19:25:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User entered empty.	System	10 Dec 2020 19:25:37

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:12
User entered empty.	System	10 Dec 2020 19:25:37

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 10:04:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 10:04:24
Data point term sent to Coder	System	25 Mar 2021 15:15:35
Coding entries removed.	Crystal Rowell (b) (4)	25 Mar 2021 15:14:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
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: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 23:48:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Dec 2020 23:48:44
Data point term sent to Coder	System	10 Dec 2020 19:27:54
User entered 'Sodium Chloride 0.9%'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:27:30

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:27:30

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:30
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Un-verified.	Crystal Rowell (b) (4)	25 Mar 2021 15:14:54
User entered 'HYPERGLYCEMIA/acute kidney injury' reason for change: Data Entry Error	Crystal Rowell (b) (4)	25 Mar 2021 15:14:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hyperglycemia'	Alexandra Caillouet	10 Dec 2020 19:27:30

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '3'	Alexandra Caillouet	10 Dec 2020 19:27:30
	(b) (4)	



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mL (mL)'	Alexandra Caillouet	10 Dec 2020 19:27:30
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:27:30

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:11:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once (ONCE)'	Alexandra Caillouet	10 Dec 2020 19:27:30
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:27:30

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:27:30

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:27:30
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:27:30

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:27:30



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:27:30
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:27:30

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:11:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:27:30
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User entered empty.	System	10 Dec 2020 19:27:30

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User entered empty.	System	10 Dec 2020 19:27:30

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:16
User entered empty.	System	10 Dec 2020 19:27:30

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE, PRODUCTSYNONYM: GLUTOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:29:23
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 Dec 2020 14:29:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:19:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:19:47
Data point term sent to Coder	System	10 Dec 2020 19:30:55
User entered 'Dextrose (Glutose) 40% gel'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:30:15

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:30:15



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hyperglycemia'	Alexandra Caillouet	10 Dec 2020 19:30:15
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '15'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:30:15

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'g (g)'	Alexandra Caillouet	10 Dec 2020 19:30:15
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:30:15

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once (ONCE)'	Alexandra Caillouet	10 Dec 2020 19:30:15
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:30:15

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Oral (ORAL)'	Alexandra Caillouet	10 Dec 2020 19:30:15
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:30:15
	(b) (4)	



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet	10 Dec 2020 19:30:15
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:30:15

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:30:15

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:30:15

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:30:15
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User entered empty.	System	10 Dec 2020 19:30:15

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User entered empty.	System	10 Dec 2020 19:30:15

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:11:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:22
User entered empty.	System	10 Dec 2020 19:30:15



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE IN WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:19:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:19:47
Data point term sent to Coder	System	10 Dec 2020 19:32:57
User entered 'Dextrose 50% in water (D50W)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:32:11

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:32:11
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hyperglycemia'	Alexandra Caillouet	10 Dec 2020 19:32:11
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '20'	Alexandra Caillouet	10 Dec 2020 19:32:11
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mL (mL)'	Alexandra Caillouet	10 Dec 2020 19:32:11
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:32:11
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once (ONCE)'	Alexandra Caillouet	10 Dec 2020 19:32:11
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:32:11
	(b) (4)	



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:32:11

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:32:11

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet	10 Dec 2020 19:32:11
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:32:11

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:32:11

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:32:11

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:32:11
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User entered empty.	System	10 Dec 2020 19:32:11



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User entered empty.	System	10 Dec 2020 19:32:11

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User entered empty.	System	10 Dec 2020 19:32:11

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE IN WATER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:19:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:19:47
Data point term sent to Coder	System	10 Dec 2020 19:34:00
User entered 'Dextrose 50% in water (D50W)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:33:05
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hyperglycemia'	Alexandra Caillouet	10 Dec 2020 19:33:05
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '50'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mL (mL)'	Alexandra Caillouet	10 Dec 2020 19:33:05
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:11:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once (ONCE)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:33:05
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet	10 Dec 2020 19:33:05
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:11:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:05

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User entered empty.	System	10 Dec 2020 19:33:05

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User entered empty.	System	10 Dec 2020 19:33:05

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:32
User entered empty.	System	10 Dec 2020 19:33:05

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:11:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:11:49
Data point term sent to Coder	System	10 Dec 2020 19:34:00
User entered 'Glucagon'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hyperglycemia'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'I'	Alexandra Caillouet	10 Dec 2020 19:33:58
	(b) (4)	



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mg (mg)'	Alexandra Caillouet	10 Dec 2020 19:33:58
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once (ONCE)'	Alexandra Caillouet	10 Dec 2020 19:33:58
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:33:58
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:33:58

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User entered empty.	System	10 Dec 2020 19:33:58

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User entered empty.	System	10 Dec 2020 19:33:58

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User entered empty.	System	10 Dec 2020 19:33:58

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:16:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:16:51
Data point term sent to Coder	System	10 Dec 2020 19:37:01
User entered 'Humalog (insulin lispro)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:00

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:00



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hyperglycemia'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:00

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '10'	Alexandra Caillouet	10 Dec 2020 19:37:00
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Other (OTHER)'	Alexandra Caillouet	10 Dec 2020 19:37:00
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Units'	Alexandra Caillouet	10 Dec 2020 19:37:00
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once (ONCE)'	Alexandra Caillouet	10 Dec 2020 19:37:00
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:00

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:00

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:00



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet	10 Dec 2020 19:37:00
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:00

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:37:00
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:00

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:37:00
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User entered empty.	System	10 Dec 2020 19:37:00

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User entered empty.	System	10 Dec 2020 19:37:00

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:11:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User entered empty.	System	10 Dec 2020 19:37:00



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN HUMAN, PRODUCTSYNONYM: HUMULIN-R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:24:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:24:44
Data point term sent to Coder	System	10 Dec 2020 19:38:02
User entered 'Insulin regular (HumuLIN R)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:57

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hyperglycemia'	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '10'	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Other (OTHER)'	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Units'	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once (ONCE)'	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:57

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:57

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:57

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:37:57

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:37:57
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User entered empty.	System	10 Dec 2020 19:37:57



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User entered empty.	System	10 Dec 2020 19:37:57

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:55
User entered empty.	System	10 Dec 2020 19:37:57

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN HUMAN, PRODUCTSYNONYM: HUMULIN-R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:24:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:24:44
Data point term sent to Coder	System	10 Dec 2020 19:39:03
User entered 'Insulin Regular (HumuLIN R)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:38:46

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:38:46
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hyperglycemia'	Alexandra Caillouet	10 Dec 2020 19:38:46
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '10'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:38:46

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Other (OTHER)'	Alexandra Caillouet	10 Dec 2020 19:38:46
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Units'	Alexandra Caillouet	10 Dec 2020 19:38:46
	(b) (4)	



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once (ONCE)'	Alexandra Caillouet	10 Dec 2020 19:38:46
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:38:46

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:38:46

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	10 Dec 2020 19:38:46

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet	10 Dec 2020 19:38:46
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:38:46

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:38:46

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '24 Nov 2020'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:38:46



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:38:46

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User entered empty.	System	10 Dec 2020 19:38:46

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User entered empty.	System	10 Dec 2020 19:38:46

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:00
User entered empty.	System	10 Dec 2020 19:38:46

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:46:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:46:57
Data point term sent to Coder	System	10 Dec 2020 19:46:09
User entered 'Lantus'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:46:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Diabetes Type II'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '40'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Other (OTHER)'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Units'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once daily (QD)'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:11:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '25 Nov 2020'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Yes (Y)'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:46:01
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 19:46:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 19:46:01

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Dec 2020 19:46:01

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:48:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:48:51
Data point term sent to Coder	System	10 Dec 2020 19:48:14
User entered 'Victoza'	Alexandra Caillouet (b) (4)	10 Dec 2020 19:47:52

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:11:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Diabetes Type II'	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '1.2'	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once daily (QD)'	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'l'	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'un May 2020'	Alexandra Caillouet	10 Dec 2020 19:47:52
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	24 Mar 2021 20:17:32
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:47:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 19:47:56
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet	10 Dec 2020 19:47:56
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:47:52
User entered empty.	Alexandra Caillouet	10 Dec 2020 19:47:52

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User entered '1'	System	10 Dec 2020 19:47:52

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:11:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User entered '1'	System	10 Dec 2020 19:47:52

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:55:16
User entered '804 (804)'	System	10 Dec 2020 19:47:52



US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:11:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:05:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 16:05:50
Data point term sent to Coder	System	11 Dec 2020 16:04:44
User entered 'Amlodipine'	Alexandra Caillouet (b) (4)	11 Dec 2020 16:03:56

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:11:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 16:04:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 16:04:10
User entered 'No (N)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	11 Dec 2020 16:04:10
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 16:03:56
User entered empty.	Alexandra Caillouet (b) (4)	11 Dec 2020 16:03:56

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Hypertension'	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '5'	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'mg (mg)'	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

US3362166

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:11:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'once daily (QD)'	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	11 Dec 2020 16:03:56



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Oral (ORAL)'	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet (b) (4)	11 Dec 2020 16:03:56

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '7 Dec 2020'	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered '0'	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'Yes (Y)'	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered empty.	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:17:32
User entered 'No (N)'	Alexandra Caillouet	11 Dec 2020 16:03:56
	(b) (4)	

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Dec 2020 16:03:56



**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Dec 2020 16:03:56

**US3362166**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:11:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Dec 2020 16:03:56

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:11:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:26
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	24 Mar 2021 20:18:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	31 Oct 2020 14:17:52
User entered 'No (N)'	(b) (4), (b) (6)	29 Aug 2020 14:27:14

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered '01 Oct 2020'	Amy Thomassie (b) (4)	31 Oct 2020 14:18:21
	(b) (4)	

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered 'tooth extraction'	Amy Thomassie (b) (4)	31 Oct 2020 14:18:21
	(b) (4)	

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered 'Adverse Event (AE)'	Amy Thomassie (b) (4)	31 Oct 2020 14:18:21
	(b) (4)	

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:11:40

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered empty.	Amy Thomassie (b) (4)	31 Oct 2020 14:18:21
	(b) (4)	

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered '01 Oct 2020'	Amy Thomassie (b) (4)	31 Oct 2020 14:18:53



US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered 'root canal'	Amy Thomassie (b) (4)	31 Oct 2020 14:18:53

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered 'Adverse Event (AE)'	Amy Thomassie (b) (4)	31 Oct 2020 14:18:53

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:11:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:54
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered empty.	Amy Thomassie (b) (4)	31 Oct 2020 14:18:53

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:56
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered '24 Nov 2020'	Amy Thomassie (b) (4)	19 Feb 2021 18:27:34

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:56
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered 'chemistry panel'	Amy Thomassie (b) (4)	19 Feb 2021 18:27:34

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:56
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered 'Diagnostic (DIAGNOSTIC)'	Amy Thomassie (b) (4)	19 Feb 2021 18:27:34

US3362166

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:11:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:44:56
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:54:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:19:08
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 18:27:34

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered	System	11 Dec 2020 20:11:16
'USA-US112-2020-MRNA-1273-P301000015'		



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Jordan'	System	11 Dec 2020 20:11:16



US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Whatley'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '5326 O'donovan dr'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'baton rouge'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '70808'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User entered 'US'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Mar 2021 18:40:05
User entered '7'	System	08 Mar 2021 16:32:28
User entered '6'	System	18 Feb 2021 17:35:30
User entered '5'	System	21 Jan 2021 14:47:26
User entered '4'	System	20 Jan 2021 19:44:29
User entered '3'	System	18 Dec 2020 15:19:06
User entered '2'	System	16 Dec 2020 15:09:53
User entered '1'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered		
'USA-US112-2020-MRNA-1273-P301000015'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Jordan'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Whatley'	System	11 Dec 2020 20:11:16



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '5326 O'donovan dr'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'baton rouge'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '70808'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User entered 'US'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Mar 2021 18:40:05
User entered '7'	System	08 Mar 2021 16:32:28
User entered '6'	System	18 Feb 2021 17:35:30
User entered '5'	System	21 Jan 2021 14:47:26
User entered '4'	System	20 Jan 2021 19:44:29
User entered '3'	System	18 Dec 2020 15:19:06
User entered '2'	System	16 Dec 2020 15:09:53
User entered '1'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
User entered '11/Dec/2020 15:11'	System	11 Dec 2020 20:11:41

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:11:40

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.		11 Dec 2020 20:11:47
User entered 'I'		11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered	System	11 Dec 2020 20:11:16
'USA-US112-2020-MRNA-1273-P301000015'		



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

Death

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Jordan'	System	11 Dec 2020 20:11:16



US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Whatley'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '5326 O'donovan dr'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'baton rouge'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '70808'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User entered 'US'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Mar 2021 18:40:05
User entered '7'	System	08 Mar 2021 16:32:28
User entered '6'	System	18 Feb 2021 17:35:30
User entered '5'	System	21 Jan 2021 14:47:26
User entered '4'	System	20 Jan 2021 19:44:29
User entered '3'	System	18 Dec 2020 15:19:06
User entered '2'	System	16 Dec 2020 15:09:53
User entered '1'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
User entered '16/Dec/2020 10:09'	System	16 Dec 2020 15:09:53

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:11:40

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.		18 Dec 2020 15:18:53
Un-reviewed for Safety.		16 Dec 2020 15:09:53
User entered '1' reason for change: New Information		16 Dec 2020 15:09:53
Reviewed for Safety.		16 Dec 2020 15:04:33
User entered '0'		16 Dec 2020 15:01:24



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered		
'USA-US112-2020-MRNA-1273-P301000015'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16



US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Jordan'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Whatley'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '5326 O'donovan dr'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'baton rouge'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '70808'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User entered 'US'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Mar 2021 18:40:05
User entered '7'	System	08 Mar 2021 16:32:28
User entered '6'	System	18 Feb 2021 17:35:30
User entered '5'	System	21 Jan 2021 14:47:26
User entered '4'	System	20 Jan 2021 19:44:29
User entered '3'	System	18 Dec 2020 15:19:06
User entered '2'	System	16 Dec 2020 15:09:53
User entered '1'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
User entered '18/Dec/2020 15:19'	System	18 Dec 2020 15:19:06



US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:11:40

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.		20 Jan 2021 19:43:54
User entered 'I'		18 Dec 2020 15:19:06

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered		
'USA-US112-2020-MRNA-1273-P301000015'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16



US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Jordan'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Whatley'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '5326 O'donovan dr'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'baton rouge'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '70808'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User entered 'US'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Mar 2021 18:40:05
User entered '7'	System	08 Mar 2021 16:32:28
User entered '6'	System	18 Feb 2021 17:35:30
User entered '5'	System	21 Jan 2021 14:47:26
User entered '4'	System	20 Jan 2021 19:44:29
User entered '3'	System	18 Dec 2020 15:19:06
User entered '2'	System	16 Dec 2020 15:09:53
User entered '1'	System	11 Dec 2020 20:11:41



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
User entered '20/Jan/2021 14:44'	System	20 Jan 2021 19:44:29

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:11:40

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.		21 Jan 2021 14:47:05
User entered 'I'		20 Jan 2021 19:44:29

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered		
'USA-US112-2020-MRNA-1273-P301000015'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16



US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Jordan'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Whatley'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '5326 O'donovan dr'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'baton rouge'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '70808'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User entered 'US'	System	11 Dec 2020 20:11:41



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Mar 2021 18:40:05
User entered '7'	System	08 Mar 2021 16:32:28
User entered '6'	System	18 Feb 2021 17:35:30
User entered '5'	System	21 Jan 2021 14:47:26
User entered '4'	System	20 Jan 2021 19:44:29
User entered '3'	System	18 Dec 2020 15:19:06
User entered '2'	System	16 Dec 2020 15:09:53
User entered '1'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
User entered '21/Jan/2021 09:47'	System	21 Jan 2021 14:47:26

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:11:40

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.		18 Feb 2021 17:35:15
User entered 'I'		21 Jan 2021 14:47:26

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered	System	11 Dec 2020 20:11:16
'USA-US112-2020-MRNA-1273-P301000015'		

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16



US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Jordan'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Whatley'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '5326 O'donovan dr'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'baton rouge'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '70808'	System	11 Dec 2020 20:11:16



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User entered 'US'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Mar 2021 18:40:05
User entered '7'	System	08 Mar 2021 16:32:28
User entered '6'	System	18 Feb 2021 17:35:30
User entered '5'	System	21 Jan 2021 14:47:26
User entered '4'	System	20 Jan 2021 19:44:29
User entered '3'	System	18 Dec 2020 15:19:06
User entered '2'	System	16 Dec 2020 15:09:53
User entered '1'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
User entered '18/Feb/2021 12:35'	System	18 Feb 2021 17:35:30

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:11:40

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.		08 Mar 2021 16:32:13
User entered 'I'		18 Feb 2021 17:35:30

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered		
'USA-US112-2020-MRNA-1273-P301000015'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Jordan'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Whatley'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '5326 O'donovan dr'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'baton rouge'	System	11 Dec 2020 20:11:16



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '70808'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User entered 'US'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Mar 2021 18:40:05
User entered '7'	System	08 Mar 2021 16:32:28
User entered '6'	System	18 Feb 2021 17:35:30
User entered '5'	System	21 Jan 2021 14:47:26
User entered '4'	System	20 Jan 2021 19:44:29
User entered '3'	System	18 Dec 2020 15:19:06
User entered '2'	System	16 Dec 2020 15:09:53
User entered '1'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
User entered '08/Mar/2021 11:32'	System	08 Mar 2021 16:32:28

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:11:40

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.		08 Mar 2021 17:54:51
User entered 'I'		08 Mar 2021 16:32:28

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered		
'USA-US112-2020-MRNA-1273-P301000015'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16



US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Yes (Y)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'No (N)'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Jordan'	System	11 Dec 2020 20:11:16

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:11:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'Whatley'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '5326 O'donovan dr'	System	11 Dec 2020 20:11:16



**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered 'baton rouge'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:11:33
User entered '70808'	System	11 Dec 2020 20:11:16

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 20:11:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:00:43
User entered 'US'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:11:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Mar 2021 18:40:05
User entered '7'	System	08 Mar 2021 16:32:28
User entered '6'	System	18 Feb 2021 17:35:30
User entered '5'	System	21 Jan 2021 14:47:26
User entered '4'	System	20 Jan 2021 19:44:29
User entered '3'	System	18 Dec 2020 15:19:06
User entered '2'	System	16 Dec 2020 15:09:53
User entered '1'	System	11 Dec 2020 20:11:41

**US3362166**

**Folder: SAE USA-US112-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 17:11:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:42:47
User entered '26/Mar/2021 14:39'	System	26 Mar 2021 18:40:05

US3362166

Folder: SAE USA-US112-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:11:40

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:24:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:42:47
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 18:40:05