

US3252261 (Prod: Centex Studies Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:12:33

All time stamps listed in this document are displayed in GMT

US3252261

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

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[Participant ID](#)

US3252261

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

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US3252261

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 01:32:12

Generated On: 09 Jun 2021 16:12:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3252261

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Date of Informed Consent ( <i>dd MMM yyyy</i> )	20 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) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

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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) 05 Mar 2021 01:32:12

Generated On: 09 Jun 2021 16:12:33

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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) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Condition	SEASONAL ALLERGIES (POLLEN, DUST)
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN JAN 1980
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 JAN 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Condition	CERVICAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN JAN 1985
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 JAN 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 1974
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1974
Start Year (derived)	1974
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 01:32:12

Generated On: 09 Jun 2021 16:12:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	20 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:12 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 08:12
Height ( <i>xxx.x</i> )	61 in
Weight ( <i>xxx.x</i> )	245 lb
BMI ( <i>xxx.x</i> )	46.38914 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 01:32:12

Generated On: 09 Jun 2021 16:12:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Date of assessment (*dd MMM yyyy*) 20 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

If No, what is the reason? Surgically sterile ☒  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN JAN 1980

Date of surgery unknown False

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

Date of last menstruation unknown False

US3252261

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 01:32:12

Generated On: 09 Jun 2021 16:12:33

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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** RETIRED

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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) 05 Mar 2021 01:32:12

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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) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187206

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) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

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) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

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)	20 AUG 2020
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 08:12
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

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)	20 AUG 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:17
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 09:40 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 09:40

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) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	09:02 (24 HR)
Collection date and time (derived)	20 AUG 2020 09:02

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 01:32:12

Generated On: 09 Jun 2021 16:12:33

Collection date ( <i>dd MMM yyyy</i> )			20 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:44	20 AUG 2020 08:44
Nasopharyngeal Swab 2	No		

US3252261

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:32:12

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**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 20 AUG 2020 10:25

PC Open Date & Time 20 AUG 2020 10:00

PC Close Date & Time 20 AUG 2020 12:30



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °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	20 AUG 2020 14:47
PC Open Date & Time	20 AUG 2020 13:25
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

21 AUG 2020 12:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

22 AUG 2020 12:14

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

23 AUG 2020 13:36

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**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

98.0 °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

24 AUG 2020 12:05

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:02

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**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

20 AUG 2020 10:25

PC Open Date & Time

20 AUG 2020 10:00

PC Close Date & Time

20 AUG 2020 12:30



US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**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

20 AUG 2020 14:48

PC Open Date & Time

20 AUG 2020 13:25

PC Close Date & Time

21 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**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

21 AUG 2020 12:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**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

22 AUG 2020 12:15

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**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

23 AUG 2020 13:38

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**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

24 AUG 2020 12:06

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**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

25 AUG 2020 12:01

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**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

26 AUG 2020 12:03

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**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 ☐



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 10:26
PC Open Date & Time	20 AUG 2020 10:00
PC Close Date & Time	20 AUG 2020 12:30

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**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 ☐

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 14:49
PC Open Date & Time	20 AUG 2020 13:25
PC Close Date & Time	21 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2034

EAB) (1725)

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:04
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2034

EAB) (1725)

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2034

EAB) (1725)



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 13:39
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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

57 of 2034

EAB) (1725)

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 12:07
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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

59 of 2034

EAB) (1725)

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**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 ☒

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:03
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3252261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3252261

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3252261

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252261

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

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)	16 SEP 2020
Time of assessment (00:00-23:59)	08:18 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:18
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	10:12 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:12
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG



US3252261

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

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.*

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 09:42 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 09:42

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

US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 SEP 2020
Collection time (00:00-23:59)	08:59 (24 HR)
Collection date and time (derived)	16 SEP 2020 08:59

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:52	16 SEP 2020 08:52
Nasopharyngeal Swab 2	No		

US3252261

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

16 SEP 2020 10:21

PC Open Date & Time

16 SEP 2020 10:02

PC Close Date & Time

16 SEP 2020 12:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °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	16 SEP 2020 13:44
PC Open Date & Time	16 SEP 2020 13:27
PC Close Date & Time	17 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

17 SEP 2020 19:25

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59



US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 SEP 2020 12:52

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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 SEP 2020 12:09

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

20 SEP 2020 13:19

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 13:35

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

22 SEP 2020 13:13

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 10:22

PC Open Date & Time

16 SEP 2020 10:02

PC Close Date & Time

16 SEP 2020 12:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**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

16 SEP 2020 13:45

PC Open Date & Time

16 SEP 2020 13:27

PC Close Date & Time

17 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**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 ☐

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

100

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

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

Yes ☒

No ☐

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

1

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

17 SEP 2020 19:28

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**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 ☐

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

1

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

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

Yes ☒

No ☐

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

1

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

18 SEP 2020 12:53

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**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 ☐

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

1

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

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

Yes ☒

No ☐

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

1

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

19 SEP 2020 12:12

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**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

20 SEP 2020 13:19

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**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

21 SEP 2020 13:35

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**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

22 SEP 2020 13:14

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**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 ☐

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 10:22
PC Open Date & Time	16 SEP 2020 10:02
PC Close Date & Time	16 SEP 2020 12:32

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**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 ☐



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 13:45
PC Open Date & Time	16 SEP 2020 13:27
PC Close Date & Time	17 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:29
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:54
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

101 of 2034

EAB) (1725)

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:13
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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

103 of 2034

EAB) (1725)



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 13:20
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 13:36
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**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 ☒

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 13:14
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3252261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252261

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3252261

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252261

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:32:11

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	07:31 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 07:31
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

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.*

US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

07:49 (24 HR)

Collection date and time (derived)

13 OCT 2020 07:49

US3252261

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:32:48

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

21 OCT 2020 10:04:09

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 20:56:38

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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	03 NOV 2020 08:50:52
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 09:32:53

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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	21 NOV 2020 15:04:00
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 09:30:02

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

06 DEC 2020 17:22:36

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

12 DEC 2020 10:04:13

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

19 DEC 2020 00:29:41

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

26 DEC 2020 12:45:20

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

03 JAN 2021 11:58:58

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

09 JAN 2021 00:23:15

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

16 JAN 2021 01:55:18

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 19:03:33

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 00:40:08
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

06 FEB 2021 10:19:29

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

13 FEB 2021 14:17:13

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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 <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 FEB 2021 12:49:10
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 10:05:35
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

06 MAR 2021 00:45:36

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 09:16:05

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

22 MAR 2021 11:53:46

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

27 MAR 2021 10:13:01

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 20:35:28

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

10 APR 2021 00:06:20

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

20 APR 2021 13:18:47

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

24 APR 2021 00:03:20

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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

01 MAY 2021 00:13:31

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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="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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JUN 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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 <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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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29 SEP 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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="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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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="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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 APR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 APR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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="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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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="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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUN 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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 <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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 726

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

No ☐

Yes ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

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07 SEP 2022 23:59



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**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 ☐

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59



US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

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

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[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

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US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3252261

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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"/>

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	22 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59

US3252261

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:12:33

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		27 FEB 2021 10:06:02

US3252261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:28:09

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3252261

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:28:09

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252261

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:28:09

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments LEFT VOICE MAIL

*If Contact Not Made, please provide Comments*

US3252261

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 20:28:09

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252261

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 20:28:09

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 19:56:40

Generated On: 09 Jun 2021 16:12:33

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



US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 19:56:40

Generated On: 09 Jun 2021 16:12:33

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) \_\_\_\_\_

US3252261

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 19:56:40

Generated On: 09 Jun 2021 16:12:33

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.*

US3252261

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 19:56:40

Generated On: 09 Jun 2021 16:12:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	07:29 (24 HR)
Collection date and time (derived)	15 MAR 2021 07:29

US3252261

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 19:56:40

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252261

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 18:53:12

Generated On: 09 Jun 2021 16:12:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3252261

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 18:53:12

Generated On: 09 Jun 2021 16:12:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3252261**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

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*

**US3252261**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3252261

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:12:33

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

**US3252261**

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

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

**Generated On: 09 Jun 2021 16:12:33**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3252261

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3252261

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 19:56:40

Generated On: 09 Jun 2021 16:12:33

Date of updated informed consent (*dd MMM yyyy*) 21 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*) 21 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 \_\_\_\_\_

US3252261

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

09:45 (24 HR)

Collection date and time (derived)

21 JAN 2021 09:45

US3252261

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	09:45
Collection Date and Time (derived)	21 JAN 2021 09:45

US3252261

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

AEID	USA-US108-2020-MRNA-1273-P30 1000017
Adverse event	HEART FAILURE
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)	1 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)	3 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	1 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	3 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT ADMITTED BECAUSE OF SHORTNESS OF BREATH, SHE STAYED IN THE HOSPITAL FOR 3 DAYS AND GOT RELEASED. WE WILL REQUEST MEDICAL RECORDS.
Serious Adverse Event Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed: (b) (4) 05 Mar 2021 20:28:08**

**Generated On: 09 Jun 2021 16:12:33**

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

---

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

Yes ☒

No ☐

---

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

---

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication METROPOLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 2005	
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) 05 Mar 2021 20:28:08

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Name of Medication LOSARTAN/HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 20:28:08

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 20:28:08

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Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 112

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 1995
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 20:28:08

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Name of Medication BABY ASPRIN

Prophylaxis Yes ☒  
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 2013	
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 (8)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Mar 2021 20:28:08

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 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 (9)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication CETIRIZINE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 2005	
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) 05 Mar 2021 20:28:08

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Name of Medication OTC VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 5000

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) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 2005	
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 (11)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication OTC VITAMIN B12

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT

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 (11)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 2005	
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 (12)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication OTC MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT

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 (12)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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 2005	
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 (13)

Data signed: (b) (4) 05 Mar 2021 20:28:08

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Name of Medication ADVAIR

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 230/21

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

355 of 2034

EAB) (1725)

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
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"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication OLMESARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

357 of 2034

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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)		03 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"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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)		03 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"/>

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication HEART FAILURE

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

361 of 2034

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

	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)		03 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"/>

US3252261

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3252261

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:12:33

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

US3252261

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:12:33

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 ☐

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

SAEID	USA-US108-2020-MRNA-1273-P301000017
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

SAEID	USA-US108-2020-MRNA-1273-P301000017
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	12/NOV/2020 19:39
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



US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 20:28:08

Generated On: 09 Jun 2021 16:12:33

SAEID	USA-US108-2020-MRNA-1273-P301000017
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/NOV/2020 10:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3252261 (Prod: Centex Studies Inc)

**US3252261**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:12:33**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'US3252261'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:19:44

US3252261

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:34:45
	(b) (4)	

US3252261

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:19:45

US3252261

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	21 Aug 2020 14:34:45
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'SCRN'	System	21 Aug 2020 14:34:45

US3252261

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:19:45



US3252261

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '75'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:12:33**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'YEARS'	System	21 Aug 2020 14:35:04

US3252261

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '75'	System	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:33

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Female (F)'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

US3252261

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:12:33**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'I'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

US3252261

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:33

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:12:33**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	



**US3252261**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:12:33**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

US3252261

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:12:33**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

US3252261

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:33

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:12:33**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

US3252261

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:33

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:04
	(b) (4)	

US3252261

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:19:47
User entered '20 Aug 2020'	Uche Ehiemua (b) (4)	20 Aug 2020 14:12:47

**US3252261**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Aug 2020'	System	20 Aug 2020 14:12:47



**US3252261**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '2020'	System	20 Aug 2020 14:12:47

**US3252261**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:33**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:19:48
User entered 'Amendment 2 (2)'	Uche Ehiemua (b) (4)	20 Aug 2020 14:12:47

**US3252261**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:19:50
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	20 Aug 2020 14:12:47

**US3252261**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:33**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:19:52
User entered empty.	Uche Ehiemua (b) (4)	20 Aug 2020 14:12:47

**US3252261**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:12:33**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:19:53
User entered empty.	Uche Ehiemua (b) (4)	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:19:55
User entered 'No (N)'	Uche Ehiemua (b) (4)	20 Aug 2020 14:12:47

US3252261

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:19:56
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:19:45

US3252261

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'I'	System	20 Aug 2020 14:13:03



US3252261

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	20 Aug 2020 14:13:03
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:12:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:35:44
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:37:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:37:25
Data point term sent to Coder	System	21 Aug 2020 14:36:48
User entered 'Hypertension'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:03
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:03
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:03
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:03
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:36:03
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:03
	(b) (4)	



**US3252261**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 2005'	System	21 Aug 2020 14:36:03

**US3252261**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '2005'	System	21 Aug 2020 14:36:03

**US3252261**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:36:03

**US3252261**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:36:03

US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:37:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	21 Aug 2020 14:37:25
User entered 'Hypothyroidism'	(b) (4)	
	System	21 Aug 2020 14:36:49
	Shannon Moyer (b) (4)	21 Aug 2020 14:36:19
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:19
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:19
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:19
	(b) (4)	



US3252261

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:36:19
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:19
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 2005'	System	21 Aug 2020 14:36:19

**US3252261**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '2005'	System	21 Aug 2020 14:36:19

**US3252261**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:36:19

**US3252261**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:36:19

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:37:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Aug 2020 14:37:25
Data point term sent to Coder	System	21 Aug 2020 14:36:49
User entered 'Asthma'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:35
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN UNK 1995'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:35
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:35
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:35
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:36:35
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:35
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 1995'	System	21 Aug 2020 14:36:35

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**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '1995'	System	21 Aug 2020 14:36:35

**US3252261**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:36:35

**US3252261**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:36:35



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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:39:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:39:18
Data point term sent to Coder	System	21 Aug 2020 14:37:50
User entered 'Gastroesophageal reflux disease'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:52

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN UNK 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:52
	(b) (4)	

US3252261

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:52
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:52
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:36:52
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:36:52
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:12:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 2020'	System	21 Aug 2020 14:36:52

**US3252261**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '2020'	System	21 Aug 2020 14:36:52



**US3252261**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:36:52

**US3252261**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:36:52

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
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)	21 Aug 2020 14:39:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 14:37:50
User entered 'Hyperlipidemia'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:09
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:09
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:09
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:09
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:37:09
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:09
	(b) (4)	



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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 2005'	System	21 Aug 2020 14:37:09

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '2005'	System	21 Aug 2020 14:37:09

**US3252261**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:37:09

**US3252261**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:37:09

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User closed query 'Per DM CLR: Please verify if this refers to Allergy to pollen,dust. If so, update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 11:29:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 16:21:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 16:21:14
Data point term sent to Coder	System	30 Sep 2020 14:42:31
Query 'Per DM CLR: Please verify if this refers to Allergy to pollen,dust. If so, update the eCRF as appropriate.' answered with 'Condition updated' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:42:12
User entered 'SEASONAL ALLERGIES (POLLEN, DUST)' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	30 Sep 2020 14:42:02
User opened query 'Per DM CLR: Please verify if this refers to Allergy to pollen,dust. If so, update the eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:29:11
Data point term sent to Coder	System	21 Aug 2020 14:37:50
User entered 'Pollen, dust (Runny nose, sneezing, congestion, watery eyes)'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN UNK 1960'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:47
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:47
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:47
	(b) (4)	



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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:37:47
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:37:47
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 1960'	System	21 Aug 2020 14:37:47

**US3252261**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '1960'	System	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:37:47

**US3252261**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered empty.	System	21 Aug 2020 14:37:47

US3252261

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:12:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:28:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Sep 2020 17:28:51
Data point term sent to Coder	System	15 Sep 2020 17:27:41
Coding entries removed.	Joanna Gurrola Mahoney (b) (4)	15 Sep 2020 17:27:33
User entered 'BILATERAL TUBAL LIGATION' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	15 Sep 2020 17:27:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:40:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Aug 2020 14:40:21
Data point term sent to Coder	System	21 Aug 2020 14:38:52
User entered 'Tubal ligation'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:11
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN Jan 1980'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:11
	(b) (4)	



**US3252261**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:11
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:11
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN Jan 1980'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:11
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:11
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 1980'	System	21 Aug 2020 14:38:11

**US3252261**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '1980'	System	21 Aug 2020 14:38:11

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 1980'	System	21 Aug 2020 14:38:11

**US3252261**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '1980'	System	21 Aug 2020 14:38:11



US3252261

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:12:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:00:42
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Associated condition added to MH' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:47:38
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:30:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 22:54:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 22:54:26
Data point term sent to Coder	System	21 Aug 2020 14:38:53
User entered 'Cervical hysterectomy'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:36

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**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN Jan 1985'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:36
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:36
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:36
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN Jan 1985'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:36
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:38:36
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 1985'	System	21 Aug 2020 14:38:36

**US3252261**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '1985'	System	21 Aug 2020 14:38:36



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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 1985'	System	21 Aug 2020 14:38:36

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '1985'	System	21 Aug 2020 14:38:36

US3252261

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:12:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:48:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:48:53
Data point term sent to Coder	System	30 Sep 2020 14:47:52
User entered 'Menorrhagia'	Uche Ehiemua (b) (4)	30 Sep 2020 14:47:00

**US3252261**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN UNK 1974'	Uche Ehiemua (b) (4)	30 Sep 2020 14:47:00
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Uche Ehiemua (b) (4)	30 Sep 2020 14:47:00
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Uche Ehiemua (b) (4)	30 Sep 2020 14:47:00
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN UNK 1985'	Uche Ehiemua (b) (4)	30 Sep 2020 14:47:00
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Uche Ehiemua (b) (4)	30 Sep 2020 14:47:00
	(b) (4)	



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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:12:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 1974'	System	30 Sep 2020 14:47:00

**US3252261**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '1974'	System	30 Sep 2020 14:47:00

**US3252261**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'Jan 1985'	System	30 Sep 2020 14:47:00

**US3252261**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '1985'	System	30 Sep 2020 14:47:00

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '08:12'	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered '20 Aug 2020 08:12'	System	21 Aug 2020 14:39:40



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '61' in	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
DataPoint set to visible.	(b) (4) System	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '245' lb	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
DataPoint set to visible.	(b) (4) System	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
Amendment Manager: User entered '46.38914'	System	17 Sep 2020 00:15:34
User entered '46.4'	System	21 Aug 2020 14:39:40
DataPoint set to visible.	System	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'kg/m2'	System	21 Aug 2020 14:39:40
DataPoint set to visible.	System	20 Aug 2020 14:13:03

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	



**US3252261**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'bpm'	System	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'breaths/min'	System	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'mmHg'	System	21 Aug 2020 14:39:40

US3252261

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered missing code ND - Not Done.	Shannon Moyer (b) (4)	21 Aug 2020 14:39:40
	(b) (4)	

**US3252261**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User entered 'mmHg'	System	21 Aug 2020 14:39:40

**US3252261**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02



**US3252261**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02

**US3252261**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:12:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:40:20
	(b) (4)	

US3252261

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:56:21
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 14:42:25
User entered '20 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:40:20

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:12:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:41:12
	(b) (4)	

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:41:12
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 18:34:24
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' answered with 'UPDATED' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	15 Sep 2020 17:26:55
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 10:04:28
User closed query 'Partner medically sterile or Other System has not been entered, however specify is provided. Please correct.' (Site from System).		21 Aug 2020 15:07:46
User opened query 'Partner medically sterile or Other System has not been entered, however specify is provided. Please correct.' (Site from System).		21 Aug 2020 14:41:12
User entered 'Surgically sterile (SURGICALLY STERILE)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:12:33

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 15:07:46
User entered 'tubal ligation'	Shannon Moyer (b) (4)	21 Aug 2020 14:41:12

US3252261

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'UN Jan 1980'	Shannon Moyer (b) (4)	21 Aug 2020 14:41:12
	(b) (4)	



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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:12:33

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:41:12
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:41:12
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:12:33

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:41:12
	(b) (4)	

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Retired'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	



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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'I'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	

US3252261

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:05:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:42:11
	(b) (4)	



**US3252261**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:31
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:31
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	21 Aug 2020 14:42:31
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'VISIT1'	System	21 Aug 2020 14:42:31

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '20 AUG 2020'	RWS_ENDPOINT	20 Aug 2020 13:39:36
	ENDPOINT (b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:33

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:47:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:47:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 13:39:36
User entered '187206' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:39:36

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:39:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	20 Aug 2020 14:13:46
	(b) (4)	



US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'No (N)'	Uche Ehiemua (b) (4)	20 Aug 2020 14:13:46
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	20 Aug 2020 14:13:46
	(b) (4)	

**US3252261**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'No (N)'	Uche Ehiemua (b) (4)	20 Aug 2020 14:13:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'No (N)'	Uche Ehiemua (b) (4)	20 Aug 2020 14:13:46
	(b) (4)	

**US3252261**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:12:33**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'No (N)'	Nancy Torrence (b) (4)	01 Oct 2020 06:39:46
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:41:08

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '08:12'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '20 Aug 2020 08:12'	System	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '98.8' F	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '78'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'bpm'	System	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '15'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'breaths/min'	System	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '116'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '74'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Sep 2020 05:13:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '10:17'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '20 Aug 2020 10:17'	System	21 Aug 2020 14:43:50



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '98.2' F	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '75'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'bpm'	System	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '15'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'breaths/min'	System	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '138'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '84'	Shannon Moyer (b) (4)	21 Aug 2020 14:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	21 Aug 2020 14:43:50

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	28 Aug 2020 16:22:06
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:44:35

US3252261

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	28 Aug 2020 16:22:06
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:44:35

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:08:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 15:08:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 15:08:44
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 15:03:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 15:03:52

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 15:03:52

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 15:03:52



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 15:08:44
User entered empty.	System	20 Aug 2020 15:03:52

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '20 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 15:03:52

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '09:40'	Joanna Gurrola Mahoney (b) (4)	20 Aug 2020 15:03:52

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '20 Aug 2020 09:40'	System	20 Aug 2020 15:03:52

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	21 Aug 2020 15:08:44
User entered empty.	(b) (4)	20 Aug 2020 15:03:52
	Joanna Gurrola Mahoney	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'ONCE'	System	21 Aug 2020 15:08:44
User entered empty.	System	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 15:08:44
User entered empty.	System	20 Aug 2020 15:03:52

US3252261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:44:57
	(b) (4)	



US3252261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:44:57
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '09:02'	Shannon Moyer (b) (4)	21 Aug 2020 14:44:57
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '20 Aug 2020 09:02'	System	21 Aug 2020 14:44:57

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:12:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '20 Aug 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:45:22
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:45:22
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '08:44'	Shannon Moyer (b) (4)	21 Aug 2020 14:45:22
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '20 Aug 2020 08:44'	System	21 Aug 2020 14:45:22



US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:45:22
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:45:22
	(b) (4)	

**US3252261**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered empty.	System	21 Aug 2020 14:45:22

US3252261

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:45:30
	(b) (4)	

US3252261

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	21 Aug 2020 14:45:30

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '426ad3a7-9ad0-47cb-903f-2cf40c9329a7'	System	20 Aug 2020 15:27:57
User entered 'Yes (Y)'	System	20 Aug 2020 15:27:57



US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '426ad3a7-9ad0-47cb-903f-2cf40c9329a7'	System	20 Aug 2020 15:27:57
User entered '98.2'	System	20 Aug 2020 15:27:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '426ad3a7-9ad0-47cb-903f-2cf40c9329a7'	System	20 Aug 2020 15:27:57
User entered 'No (N)'	System	20 Aug 2020 15:27:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:48', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '426ad3a7-9ad0-47cb-903f-2cf40c9329a7'	System	20 Aug 2020 15:27:57
User entered '20 Aug 2020 10:25'	System	20 Aug 2020 15:27:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Aug 2020 10:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Aug 2020 12:30'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d66b0d0-7896-43ee-8773-ad385ba36325'	System	20 Aug 2020 19:49:41
User entered 'Yes (Y)'	System	20 Aug 2020 19:49:41

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d66b0d0-7896-43ee-8773-ad385ba36325'	System	20 Aug 2020 19:49:41
User entered '97.3'	System	20 Aug 2020 19:49:41



US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:27', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d66b0d0-7896-43ee-8773-ad385ba36325'	System	20 Aug 2020 19:49:41
User entered 'No (N)'	System	20 Aug 2020 19:49:41

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:34', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d66b0d0-7896-43ee-8773-ad385ba36325'	System	20 Aug 2020 19:49:41
User entered '20 Aug 2020 14:47'	System	20 Aug 2020 19:49:41

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Aug 2020 13:25'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 2'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:02:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '32e0f9c5-bb7a-40d3-9bba-050b9475bf8a'	System	21 Aug 2020 17:05:15
User entered 'Yes (Y)'	System	21 Aug 2020 17:05:15

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:02:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '32e0f9c5-bb7a-40d3-9bba-050b9475bf8a'	System	21 Aug 2020 17:05:15
User entered '97.7'	System	21 Aug 2020 17:05:15

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:02:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '32e0f9c5-bb7a-40d3-9bba-050b9475bf8a'	System	21 Aug 2020 17:05:15
User entered 'No (N)'	System	21 Aug 2020 17:05:15



US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:02', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '32e0f9c5-bb7a-40d3-9bba-050b9475bf8a'	System	21 Aug 2020 17:05:15
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 17:05:15

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 3'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:13:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'ebe8d011-ecca-413d-9d73-4a513cd95845'	System	22 Aug 2020 17:16:12
User entered 'Yes (Y)'	System	22 Aug 2020 17:16:12

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:13:53', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'ebe8d011-ecca-413d-9d73-4a513cd95845'	System	22 Aug 2020 17:16:12
User entered '97.7'	System	22 Aug 2020 17:16:12

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:13:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'ebe8d011-ecca-413d-9d73-4a513cd95845'	System	22 Aug 2020 17:16:12
User entered 'No (N)'	System	22 Aug 2020 17:16:12

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:14:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'ebe8d011-ecca-413d-9d73-4a513cd95845'	System	22 Aug 2020 17:16:12
User entered '22 Aug 2020 12:14'	System	22 Aug 2020 17:16:12



US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 4'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:34:07', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '884bf57e-6327-4876-8786-16e4f18441a6'	System	23 Aug 2020 18:38:39
User entered 'Yes (Y)'	System	23 Aug 2020 18:38:39

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:36:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '884bf57e-6327-4876-8786-16e4f18441a6'	System	23 Aug 2020 18:38:39
User entered '97.2'	System	23 Aug 2020 18:38:39

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:36:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '884bf57e-6327-4876-8786-16e4f18441a6'	System	23 Aug 2020 18:38:39
User entered 'No (N)'	System	23 Aug 2020 18:38:39

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:36:31', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '884bf57e-6327-4876-8786-16e4f18441a6'	System	23 Aug 2020 18:38:39
User entered '23 Aug 2020 13:36'	System	23 Aug 2020 18:38:39

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:03:52



US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 5'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a7b9cdaf-c26c-43d7-b79c-3756067652fe'	System	24 Aug 2020 17:07:43
User entered 'Yes (Y)'	System	24 Aug 2020 17:07:43

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a7b9cdaf-c26c-43d7-b79c-3756067652fe'	System	24 Aug 2020 17:07:43
User entered '98.0'	System	24 Aug 2020 17:07:43

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:20', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a7b9cdaf-c26c-43d7-b79c-3756067652fe'	System	24 Aug 2020 17:07:43
User entered 'No (N)'	System	24 Aug 2020 17:07:43

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a7b9cdaf-c26c-43d7-b79c-3756067652fe'	System	24 Aug 2020 17:07:43
User entered '24 Aug 2020 12:05'	System	24 Aug 2020 17:07:43

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:03:52



US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 6'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:00:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58ba3c62-cd71-44b7-a334-9054cf48cebb'	System	25 Aug 2020 17:02:57
User entered 'Yes (Y)'	System	25 Aug 2020 17:02:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:00:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58ba3c62-cd71-44b7-a334-9054cf48cebb'	System	25 Aug 2020 17:02:57
User entered '97.0'	System	25 Aug 2020 17:02:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:00:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58ba3c62-cd71-44b7-a334-9054cf48cebb'	System	25 Aug 2020 17:02:57
User entered 'No (N)'	System	25 Aug 2020 17:02:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:00:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58ba3c62-cd71-44b7-a334-9054cf48cebb'	System	25 Aug 2020 17:02:57
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:02:57

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 7'	System	20 Aug 2020 15:03:52



US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:02:37', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '760568fb-52e3-4b30-b45d-92bb038e4070'	System	26 Aug 2020 17:05:07
User entered 'Yes (Y)'	System	26 Aug 2020 17:05:07

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:02:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '760568fb-52e3-4b30-b45d-92bb038e4070'	System	26 Aug 2020 17:05:07
User entered '97.9'	System	26 Aug 2020 17:05:07

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:02:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '760568fb-52e3-4b30-b45d-92bb038e4070'	System	26 Aug 2020 17:05:07
User entered 'No (N)'	System	26 Aug 2020 17:05:07

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:02:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '760568fb-52e3-4b30-b45d-92bb038e4070'	System	26 Aug 2020 17:05:07
User entered '26 Aug 2020 12:02'	System	26 Aug 2020 17:05:07

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered 'None (1)'	System	20 Aug 2020 15:28:07



US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered 'No (N)'	System	20 Aug 2020 15:28:07

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered 'No (N)'	System	20 Aug 2020 15:28:07

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:57', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered 'None (1)'	System	20 Aug 2020 15:28:07

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:25:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f2d77a17-2099-4efd-9da0-f015b5b43d53'	System	20 Aug 2020 15:28:07
User entered '20 Aug 2020 10:25'	System	20 Aug 2020 15:28:07

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Aug 2020 10:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Aug 2020 12:30'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:45', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered 'None (1)'	System	20 Aug 2020 19:50:25



US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered 'No (N)'	System	20 Aug 2020 19:50:25

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:47:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered 'No (N)'	System	20 Aug 2020 19:50:25

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered 'None (1)'	System	20 Aug 2020 19:50:25

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e6d08d17-24e3-4431-8243-a1e0dadf1b69'	System	20 Aug 2020 19:50:25
User entered '20 Aug 2020 14:48'	System	20 Aug 2020 19:50:25

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Aug 2020 13:25'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 2'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 17:06:04



US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered 'No (N)'	System	21 Aug 2020 17:06:04

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered 'No (N)'	System	21 Aug 2020 17:06:04

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:46', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered 'None (1)'	System	21 Aug 2020 17:06:04

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:03:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a2732d2e-7753-4b61-9400-ebcc0dc7dce7'	System	21 Aug 2020 17:06:04
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 17:06:04

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 3'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:14:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 17:17:33



US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered 'No (N)'	System	22 Aug 2020 17:17:33

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered 'No (N)'	System	22 Aug 2020 17:17:33

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered 'None (1)'	System	22 Aug 2020 17:17:33

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1b231cd1-c635-4c32-a547-9fbb82348919'	System	22 Aug 2020 17:17:33
User entered '22 Aug 2020 12:15'	System	22 Aug 2020 17:17:33

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 4'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:37:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 18:40:15



US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:37:37', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered 'No (N)'	System	23 Aug 2020 18:40:15

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:37:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered 'No (N)'	System	23 Aug 2020 18:40:15

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:37:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered 'None (1)'	System	23 Aug 2020 18:40:15

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7bee63a8-a5a6-4b7f-9216-1562e5e5596b'	System	23 Aug 2020 18:40:15
User entered '23 Aug 2020 13:38'	System	23 Aug 2020 18:40:15

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 5'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered 'None (1)'	System	24 Aug 2020 17:08:11



US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered 'No (N)'	System	24 Aug 2020 17:08:11

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered 'No (N)'	System	24 Aug 2020 17:08:11

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:05:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered 'None (1)'	System	24 Aug 2020 17:08:11

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a59ea904-150e-415d-9c53-6b0af6b7deae'	System	24 Aug 2020 17:08:11
User entered '24 Aug 2020 12:06'	System	24 Aug 2020 17:08:11

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 6'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:00:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered 'None (1)'	System	25 Aug 2020 17:03:22



US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered 'No (N)'	System	25 Aug 2020 17:03:22

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered 'No (N)'	System	25 Aug 2020 17:03:22

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered 'None (1)'	System	25 Aug 2020 17:03:22

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:12', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'be597e3b-f46b-443b-ba5e-b5e3d8682b4e'	System	25 Aug 2020 17:03:22
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 17:03:22

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 7'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:06', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered 'None (1)'	System	26 Aug 2020 17:05:31



US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:10', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered 'No (N)'	System	26 Aug 2020 17:05:31

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:15', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered 'No (N)'	System	26 Aug 2020 17:05:31

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered 'None (1)'	System	26 Aug 2020 17:05:31

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:23', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9bbda636-1775-42d9-b456-5cbe1ff96762'	System	26 Aug 2020 17:05:31
User entered '26 Aug 2020 12:03'	System	26 Aug 2020 17:05:31

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:12', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'None (0)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:15', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered 'No (N)'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T10:26:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f75b6b68-1afa-4b0f-b104-12f6a4104be0'	System	20 Aug 2020 15:28:26
User entered '20 Aug 2020 10:26'	System	20 Aug 2020 15:28:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Aug 2020 10:00'	System	20 Aug 2020 15:03:52



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Aug 2020 12:30'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:23', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:30', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:34', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:43', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'None (0)'	System	20 Aug 2020 19:51:26



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:48:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered 'No (N)'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-20T14:49:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'aab260bf-3b46-44c0-a613-d912ce8b9f51'	System	20 Aug 2020 19:51:26
User entered '20 Aug 2020 14:49'	System	20 Aug 2020 19:51:26

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Aug 2020 13:25'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 2'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:31', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'None (0)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered 'No (N)'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-21T12:04:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b1858cbb-4c97-4533-bc9d-38798546f56d'	System	21 Aug 2020 17:07:06
User entered '21 Aug 2020 12:04'	System	21 Aug 2020 17:07:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 3'	System	20 Aug 2020 15:03:52



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:53', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:15:57', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'None (0)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:16:06', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered 'No (N)'	System	22 Aug 2020 17:18:21

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-22T12:16:12', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '815d2372-a4fd-4673-bc30-4b8b36d1b3e3'	System	22 Aug 2020 17:18:21
User entered '22 Aug 2020 12:16'	System	22 Aug 2020 17:18:21



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 4'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:39:07', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'None (0)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:38:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered 'No (N)'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-23T13:39:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5a253040-cf2f-406e-9a8e-aef3ae1a57bd'	System	23 Aug 2020 18:41:22
User entered '23 Aug 2020 13:39'	System	23 Aug 2020 18:41:22

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 5'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:24', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:30', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:45', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'None (0)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:06:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered 'No (N)'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-24T12:07:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '07396209-94ff-40f1-a32d-98d8150498fb'	System	24 Aug 2020 17:09:11
User entered '24 Aug 2020 12:07'	System	24 Aug 2020 17:09:11

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:03:52



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 6'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:30', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'None (0)'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered 'No (N)'	System	25 Aug 2020 17:03:53



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-25T12:01:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0d76d50a-c60c-41c5-a367-c65fc81b1b65'	System	25 Aug 2020 17:03:53
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 17:03:53

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

**US3252261**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:12:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 7'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:32', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06



US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'None (0)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered 'No (N)'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-08-26T12:03:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f1267e31-2f56-4121-8377-b2209e262ba4'	System	26 Aug 2020 17:06:06
User entered '26 Aug 2020 12:03'	System	26 Aug 2020 17:06:06

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:03:52

US3252261

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:03:52

**US3252261**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	28 Aug 2020 16:22:29
	(b) (4)	

US3252261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '27 Aug 2020'	Shannon Moyer (b) (4)	28 Aug 2020 16:22:29
	(b) (4)	



US3252261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	28 Aug 2020 16:22:29
	(b) (4)	

US3252261

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	28 Aug 2020 16:22:29
	(b) (4)	

US3252261

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	28 Aug 2020 16:22:36
	(b) (4)	

US3252261

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	28 Aug 2020 16:22:36

**US3252261**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	06 Sep 2020 03:46:25
	(b) (4)	

US3252261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '4 Sep 2020'	Shannon Moyer (b) (4)	06 Sep 2020 03:46:25
	(b) (4)	

US3252261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	06 Sep 2020 03:46:25
	(b) (4)	

US3252261

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Shannon Moyer (b) (4)	06 Sep 2020 03:46:25
	(b) (4)	



US3252261

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	06 Sep 2020 03:46:31
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	06 Sep 2020 03:46:31

US3252261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	11 Sep 2020 04:12:36
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '10 Sep 2020'	Nancy Torrence (b) (4)	11 Sep 2020 04:12:36
	(b) (4)	

US3252261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	11 Sep 2020 04:12:36
	(b) (4)	

US3252261

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Nancy Torrence (b) (4)	11 Sep 2020 04:12:36
	(b) (4)	

US3252261

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	11 Sep 2020 04:12:41
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	11 Sep 2020 04:12:41



US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	16 Sep 2020 14:42:25

US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 14:48:48
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."		17 Sep 2020 00:15:33
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'initial date is correct.' (Site from System).	Joanna Gurrola Mahoney (b) (4)	16 Sep 2020 14:43:24
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 14:42:25
User entered '16 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	16 Sep 2020 14:42:25

US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	16 Sep 2020 14:42:25

US3252261

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'VISIT2'	System	16 Sep 2020 14:42:25

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '16 Sep 2020'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '08:18'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	



US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '16 Sep 2020 08:18'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '97.9' F	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '73'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'bpm'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '16'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'breaths/min'	System	17 Sep 2020 03:34:23



US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '157'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '84'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '16 Sep 2020'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '10:12'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	



US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '16 Sep 2020 10:12'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '97.1' F	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '63'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'bpm'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '18'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'breaths/min'	System	17 Sep 2020 03:34:23



US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '158'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '78'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:23
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	17 Sep 2020 03:34:23

US3252261

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'No (N)'	Shannon Moyer (b) (4)	17 Sep 2020 03:34:35
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Shannon Moyer (b) (4)	17 Sep 2020 03:34:35
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Joanna Gurrola Mahoney	16 Sep 2020 15:15:07
	(b) (4)	



US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Joanna Gurrola Mahoney (b) (4)	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '16 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '09:42'	Joanna Gurrola Mahoney	16 Sep 2020 15:15:07
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '16 Sep 2020 09:42'	System	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney	16 Sep 2020 15:15:07
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'ONCE'	System	16 Sep 2020 15:15:07

US3252261

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 15:15:07



US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	17 Sep 2020 03:35:04
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16SEP2020 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)	25 Nov 2020 06:56:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16SEP2020 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 'AWB Number: 914897844496' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 23:02:35
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16SEP2020 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)	19 Oct 2020 06:36:59
User entered '16 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:04

US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '08:59'	Shannon Moyer (b) (4)	17 Sep 2020 03:35:04
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '16 Sep 2020 08:59'	System	17 Sep 2020 03:35:04

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:12:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 16SEP2020 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)	27 Nov 2020 09:52:39
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 16SEP2020 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 'Sample dated 16SEP2020 was collected for Visit2 Day 29 using an UNSCHEDULED kit due to unavailable Type A kits.' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	30 Oct 2020 19:36:22
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 16SEP2020 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 04:59:30
User entered '16 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:33

**US3252261**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	17 Sep 2020 03:35:33
	(b) (4)	

**US3252261**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:12:33**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '08:52'	Shannon Moyer (b) (4)	17 Sep 2020 03:35:33
	(b) (4)	



**US3252261**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '16 Sep 2020 08:52'	System	17 Sep 2020 03:35:33

**US3252261**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'No (N)'	Shannon Moyer (b) (4)	17 Sep 2020 03:35:33
	(b) (4)	

US3252261

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Shannon Moyer (b) (4)	17 Sep 2020 03:35:33
	(b) (4)	

**US3252261**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered empty.	System	17 Sep 2020 03:35:33

US3252261

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	17 Sep 2020 03:35:40
	(b) (4)	

**US3252261**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	17 Sep 2020 03:35:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '224dd224-ca83-410a-92a9-4d9d80fadb8b'	System	16 Sep 2020 15:23:40
User entered 'Yes (Y)'	System	16 Sep 2020 15:23:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:20:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '224dd224-ca83-410a-92a9-4d9d80fadb8b' User entered '97.1'	System	16 Sep 2020 15:23:40
	System	16 Sep 2020 15:23:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:20:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '224dd224-ca83-410a-92a9-4d9d80fadb8b'	System	16 Sep 2020 15:23:40
User entered 'No (N)'	System	16 Sep 2020 15:23:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '224dd224-ca83-410a-92a9-4d9d80fadb8b'	System	16 Sep 2020 15:23:40
User entered '16 Sep 2020 10:21'	System	16 Sep 2020 15:23:40

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '16 Sep 2020 10:02'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '16 Sep 2020 12:32'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:44:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9b24b7ba-0087-4665-b6d9-7e21f797fcc2'	System	16 Sep 2020 18:47:20
User entered 'Yes (Y)'	System	16 Sep 2020 18:47:20



US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:44:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9b24b7ba-0087-4665-b6d9-7e21f797fcc2'	System	16 Sep 2020 18:47:20
User entered '97.2'	System	16 Sep 2020 18:47:20

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:44:43', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9b24b7ba-0087-4665-b6d9-7e21f797fcc2'	System	16 Sep 2020 18:47:20
User entered 'No (N)'	System	16 Sep 2020 18:47:20

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:44:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9b24b7ba-0087-4665-b6d9-7e21f797fcc2'	System	16 Sep 2020 18:47:20
User entered '16 Sep 2020 13:44'	System	16 Sep 2020 18:47:20

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '16 Sep 2020 13:27'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 2'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:25:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'bc72bdaf-0c7c-4f94-9ef2-9deb1feb5321'	System	18 Sep 2020 00:28:30
User entered 'Yes (Y)'	System	18 Sep 2020 00:28:30

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:25:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'bc72bdaf-0c7c-4f94-9ef2-9deb1feb5321'	System	18 Sep 2020 00:28:30
User entered '97.7'	System	18 Sep 2020 00:28:30



US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:25:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'bc72bdaf-0c7c-4f94-9ef2-9deb1feb5321'	System	18 Sep 2020 00:28:30
User entered 'No (N)'	System	18 Sep 2020 00:28:30

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:25:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'bc72bdaf-0c7c-4f94-9ef2-9deb1feb5321'	System	18 Sep 2020 00:28:30
User entered '17 Sep 2020 19:25'	System	18 Sep 2020 00:28:30

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 3'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:52:07', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd2f438de-b88f-4756-8a94-fdd2eee145fe'	System	18 Sep 2020 17:55:04
User entered 'Yes (Y)'	System	18 Sep 2020 17:55:04

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:52:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd2f438de-b88f-4756-8a94-fdd2eee145fe'	System	18 Sep 2020 17:55:04
User entered '97.7'	System	18 Sep 2020 17:55:04

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:52:27', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd2f438de-b88f-4756-8a94-fdd2eee145fe'	System	18 Sep 2020 17:55:04
User entered 'No (N)'	System	18 Sep 2020 17:55:04



US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:52:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd2f438de-b88f-4756-8a94-fdd2eee145fe'	System	18 Sep 2020 17:55:04
User entered '18 Sep 2020 12:52'	System	18 Sep 2020 17:55:04

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 4'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:08:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '95637890-ab10-4be4-b31f-f972108ba98c'	System	19 Sep 2020 17:12:01
User entered 'Yes (Y)'	System	19 Sep 2020 17:12:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:09:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '95637890-ab10-4be4-b31f-f972108ba98c'	System	19 Sep 2020 17:12:01
User entered '97.2'	System	19 Sep 2020 17:12:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:09:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '95637890-ab10-4be4-b31f-f972108ba98c'	System	19 Sep 2020 17:12:01
User entered 'No (N)'	System	19 Sep 2020 17:12:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:09:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '95637890-ab10-4be4-b31f-f972108ba98c'	System	19 Sep 2020 17:12:01
User entered '19 Sep 2020 12:09'	System	19 Sep 2020 17:12:01



US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 5'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8a25dd0c-19ae-41d1-aaba-a8895af60031'	System	20 Sep 2020 18:21:52
User entered 'Yes (Y)'	System	20 Sep 2020 18:21:52

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8a25dd0c-19ae-41d1-aaba-a8895af60031'	System	20 Sep 2020 18:21:52
User entered '97.0'	System	20 Sep 2020 18:21:52

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8a25dd0c-19ae-41d1-aaba-a8895af60031'	System	20 Sep 2020 18:21:52
User entered 'No (N)'	System	20 Sep 2020 18:21:52

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:23', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8a25dd0c-19ae-41d1-aaba-a8895af60031'	System	20 Sep 2020 18:21:52
User entered '20 Sep 2020 13:19'	System	20 Sep 2020 18:21:52

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 6'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:34:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '807cc5f2-3fb6-4a88-bfbb-06cf48fdcc07'	System	21 Sep 2020 18:37:32
User entered 'Yes (Y)'	System	21 Sep 2020 18:37:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:34:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '807cc5f2-3fb6-4a88-bfbb-06cf48fdcc07'	System	21 Sep 2020 18:37:32
User entered '97.0'	System	21 Sep 2020 18:37:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:34:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '807cc5f2-3fb6-4a88-bfbb-06cf48fdcc07'	System	21 Sep 2020 18:37:32
User entered 'No (N)'	System	21 Sep 2020 18:37:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '807cc5f2-3fb6-4a88-bfbb-06cf48fdcc07'	System	21 Sep 2020 18:37:32
User entered '21 Sep 2020 13:35'	System	21 Sep 2020 18:37:32

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 7'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:06', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2f91792f-1a2a-47c3-bcf4-e436f0c437b3'	System	22 Sep 2020 18:16:01
User entered 'Yes (Y)'	System	22 Sep 2020 18:16:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:16', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2f91792f-1a2a-47c3-bcf4-e436f0c437b3'	System	22 Sep 2020 18:16:01
User entered '96.6'	System	22 Sep 2020 18:16:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:20', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2f91792f-1a2a-47c3-bcf4-e436f0c437b3'	System	22 Sep 2020 18:16:01
User entered 'No (N)'	System	22 Sep 2020 18:16:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:31', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2f91792f-1a2a-47c3-bcf4-e436f0c437b3'	System	22 Sep 2020 18:16:01
User entered '22 Sep 2020 13:13'	System	22 Sep 2020 18:16:01

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:24', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69'	System	16 Sep 2020 15:24:32
User entered 'None (1)'	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:43', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69'	System	16 Sep 2020 15:24:32
User entered 'No (N)'	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69'	System	16 Sep 2020 15:24:32
User entered 'No (N)'	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:21:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69'	System	16 Sep 2020 15:24:32
User entered 'None (1)'	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '666cbc04-f40a-4b17-9202-d18369e53c69' User entered '16 Sep 2020 10:22'	System	16 Sep 2020 15:24:32
	System	16 Sep 2020 15:24:32

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '16 Sep 2020 10:02'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '16 Sep 2020 12:32'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:44:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered 'None (1)'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered 'No (N)'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered 'No (N)'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:12', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered 'None (1)'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:16', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8adb1486-0754-4c39-bba1-874ab35c9dd5'	System	16 Sep 2020 18:47:45
User entered '16 Sep 2020 13:45'	System	16 Sep 2020 18:47:45

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '16 Sep 2020 13:27'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 2'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:26:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:26:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered 'Yes (Y)'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:26:51', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered '100'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:26:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered 'Yes (Y)'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:21', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered '1'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered 'None (1)'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:32', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '17b56a2f-aea2-41ab-9686-258a37d04cd5'	System	18 Sep 2020 00:31:01
User entered '17 Sep 2020 19:28'	System	18 Sep 2020 00:31:01

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 3'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:52:46', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered 'Yes (Y)'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered '1'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered 'Yes (Y)'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered '1'	System	18 Sep 2020 17:56:21

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:47', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered 'None (1)'	System	18 Sep 2020 17:56:21



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:53:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0849615f-158e-45e5-8fb5-872e62e140f2'	System	18 Sep 2020 17:56:21
User entered '18 Sep 2020 12:53'	System	18 Sep 2020 17:56:21

**US3252261**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:12:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 4'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:09:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f'	System	19 Sep 2020 17:14:44
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:09:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f'	System	19 Sep 2020 17:14:44
User entered 'Yes (Y)'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:10:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f' User entered '1'	System	19 Sep 2020 17:14:44
	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:10:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f'	System	19 Sep 2020 17:14:44
User entered 'Yes (Y)'	System	19 Sep 2020 17:14:44



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:11:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f' User entered '1'	System	19 Sep 2020 17:14:44
	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f'	System	19 Sep 2020 17:14:44
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '97343e23-da89-4943-8d11-3ca88d4a3d9f' User entered '19 Sep 2020 12:12'	System	19 Sep 2020 17:14:44
	System	19 Sep 2020 17:14:44

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 5'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered 'None (1)'	System	20 Sep 2020 18:22:12

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered 'No (N)'	System	20 Sep 2020 18:22:12



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:37', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered 'No (N)'	System	20 Sep 2020 18:22:12

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered 'None (1)'	System	20 Sep 2020 18:22:12

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'f9584b0c-3e95-4cfc-bccd-55d302a1402a'	System	20 Sep 2020 18:22:12
User entered '20 Sep 2020 13:19'	System	20 Sep 2020 18:22:12

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 6'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered 'None (1)'	System	21 Sep 2020 18:38:19

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered 'No (N)'	System	21 Sep 2020 18:38:19



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered 'No (N)'	System	21 Sep 2020 18:38:19

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered 'None (1)'	System	21 Sep 2020 18:38:19

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:48', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '991dfc8f-c75a-4d88-81be-5fd3dbbe72c6'	System	21 Sep 2020 18:38:19
User entered '21 Sep 2020 13:35'	System	21 Sep 2020 18:38:19

**US3252261**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:12:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 7'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered 'None (1)'	System	22 Sep 2020 18:16:37

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:45', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered 'No (N)'	System	22 Sep 2020 18:16:37



US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered 'No (N)'	System	22 Sep 2020 18:16:37

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:13:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered 'None (1)'	System	22 Sep 2020 18:16:37

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e41c7cff-a062-4293-a138-090ef062a9fa'	System	22 Sep 2020 18:16:37
User entered '22 Sep 2020 13:14'	System	22 Sep 2020 18:16:37

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:21', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'None (0)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:34', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered 'No (N)'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T10:22:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '8cc87895-a87a-424d-b078-aa5c81087bb8'	System	16 Sep 2020 15:25:07
User entered '16 Sep 2020 10:22'	System	16 Sep 2020 15:25:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '16 Sep 2020 10:02'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '16 Sep 2020 12:32'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:22', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:28', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:32', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:39', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'None (0)'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:43', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered 'No (N)'	System	16 Sep 2020 18:48:20



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-16T13:45:48', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '91b7390b-0d14-46c4-9558-898b73540836'	System	16 Sep 2020 18:48:20
User entered '16 Sep 2020 13:45'	System	16 Sep 2020 18:48:20

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '16 Sep 2020 13:27'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 2'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:45', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:53', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:28:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:29:02', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:29:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'None (0)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:29:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered 'No (N)'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-17T19:29:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '13bef284-aaaf-4c1a-a376-ff66704bf3cb'	System	18 Sep 2020 00:31:43
User entered '17 Sep 2020 19:29'	System	18 Sep 2020 00:31:43

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 3'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:07', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:15', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:19', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:23', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'None (0)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered 'No (N)'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-18T12:54:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'e15ccd38-180f-40c9-a997-9969e69f4c1f'	System	18 Sep 2020 17:57:05
User entered '18 Sep 2020 12:54'	System	18 Sep 2020 17:57:05

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 4'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:21', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:31', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f' User entered 'None (0)'	System	19 Sep 2020 17:15:39
	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:35', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:12:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'None (0)'	System	19 Sep 2020 17:15:39



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:13:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered 'No (N)'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-19T12:13:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2e48e6c8-16d9-4d6d-b62f-e8e41ab9a34f'	System	19 Sep 2020 17:15:39
User entered '19 Sep 2020 12:13'	System	19 Sep 2020 17:15:39

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 5'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:19:59', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:20:02', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:20:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'None (0)'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:20:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered 'No (N)'	System	20 Sep 2020 18:22:40

**US3252261**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:12:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-20T13:20:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '61051972-da29-4fef-9fb9-b0a760b7e1bc'	System	20 Sep 2020 18:22:40
User entered '20 Sep 2020 13:20'	System	20 Sep 2020 18:22:40

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 6'	System	16 Sep 2020 15:15:07



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:35:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:05', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:21', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'None (0)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:26', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered 'No (N)'	System	21 Sep 2020 18:39:09

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-21T13:36:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '27b8f7a8-6926-4bcb-bff1-5667845d075e'	System	21 Sep 2020 18:39:09
User entered '21 Sep 2020 13:36'	System	21 Sep 2020 18:39:09



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:12:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	16 Sep 2020 15:15:07
User entered 'Day 7'	System	16 Sep 2020 15:15:07

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:30', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:40', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27



US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:44', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'None (0)'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:49', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered 'No (N)'	System	22 Sep 2020 18:17:27

**US3252261**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:12:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-09-22T13:14:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cfd66afc-51ae-4820-b8bf-242178634f6d'	System	22 Sep 2020 18:17:27
User entered '22 Sep 2020 13:14'	System	22 Sep 2020 18:17:27

US3252261

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:12:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:15:07

**US3252261**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:12:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:15:07

**US3252261**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	24 Sep 2020 05:01:11
	(b) (4)	

US3252261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '23 Sep 2020'	Nancy Torrence (b) (4)	24 Sep 2020 05:01:11
	(b) (4)	

US3252261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	24 Sep 2020 05:01:11
	(b) (4)	



US3252261

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:11
	(b) (4)	

US3252261

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	24 Sep 2020 05:01:17
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	24 Sep 2020 05:01:17

**US3252261**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	01 Oct 2020 06:40:09
	(b) (4)	

US3252261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '30 Sep 2020'	Nancy Torrence (b) (4)	01 Oct 2020 06:40:09
	(b) (4)	

US3252261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	01 Oct 2020 06:40:09
	(b) (4)	

US3252261

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Nancy Torrence (b) (4)	01 Oct 2020 06:40:09
	(b) (4)	

US3252261

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	01 Oct 2020 06:40:17
	(b) (4)	



**US3252261**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	01 Oct 2020 06:40:17

US3252261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	08 Oct 2020 05:20:08
	(b) (4)	

US3252261

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered '7 Oct 2020'	Nancy Torrence (b) (4)	08 Oct 2020 05:20:08
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	08 Oct 2020 05:20:08
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered empty.	Nancy Torrence (b) (4)	08 Oct 2020 05:20:08
	(b) (4)	

US3252261

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:12
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	08 Oct 2020 05:20:12
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	08 Oct 2020 05:20:12

**US3252261**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 17:10:01
	(b) (4)	



US3252261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '13 Oct 2020'	Nancy Torrence (b) (4)	13 Oct 2020 17:10:01
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4)	13 Oct 2020 17:10:01
	(b) (4)	

**US3252261**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'VISIT3'	System	13 Oct 2020 17:10:01

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '13 Oct 2020'	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '07:31' reason for change: Data Entry	Nancy Torrence (b) (4)	13 Oct 2020 23:59:13
Error	(b) (4)	
User entered '07:26'	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	

**US3252261**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '13 Oct 2020 07:31'	System	13 Oct 2020 23:59:13
User entered '13 Oct 2020 07:26'	System	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '97.8' F	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	



US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '70'	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'bpm'	System	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '15'	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'breaths/min'	System	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '126'	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	13 Oct 2020 17:11:53



US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '85'	Nancy Torrence (b) (4)	13 Oct 2020 17:11:53
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'mmHg'	System	13 Oct 2020 17:11:53

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43

US3252261

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43

US3252261

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'No (N)'	Nancy Torrence (b) (4)	13 Oct 2020 17:12:02
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered empty.	Nancy Torrence (b) (4)	13 Oct 2020 17:12:02
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 17:12:23
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:47:29
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Samples have been scanned in with requisition number 1F653176943 and all samples have been received at PPD. Reports were sent back on 12FEB2021' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	19 Feb 2021 17:35:03
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:20:22
User entered '13 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	13 Oct 2020 17:12:23



US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered '07:49'	Nancy Torrence (b) (4)	13 Oct 2020 17:12:23
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered '13 Oct 2020 07:49'	System	13 Oct 2020 17:12:23

US3252261

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 01:32:48
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 17:12:29
	(b) (4)	

US3252261

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	13 Oct 2020 17:12:29

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 64'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-10-21T10:03:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d6e0bf5-1e43-44de-b5d2-f317361c9df1'	System	21 Oct 2020 15:06:56
User entered 'No (N)'	System	21 Oct 2020 15:06:56

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

Have you been exposed to someone with 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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-10-21T10:04:01', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d6e0bf5-1e43-44de-b5d2-f317361c9df1'	System	21 Oct 2020 15:06:56
User entered 'No (N)'	System	21 Oct 2020 15:06:56

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-10-21T10:04:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3d6e0bf5-1e43-44de-b5d2-f317361c9df1'	System	21 Oct 2020 15:06:56
User entered '21 Oct 2020 10:04:09'	System	21 Oct 2020 15:06:56



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 15:03:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 15:03:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 71'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

[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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-10-27T20:56:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5b44d435-a158-439e-bb8e-bb6b9ba1a1c9'	System	28 Oct 2020 01:59:23
User entered 'No (N)'	System	28 Oct 2020 01:59:23

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

Have you been exposed to someone with 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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-10-27T20:56:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5b44d435-a158-439e-bb8e-bb6b9ba1a1c9'	System	28 Oct 2020 01:59:23
User entered 'No (N)'	System	28 Oct 2020 01:59:23

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-10-27T20:56:38', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5b44d435-a158-439e-bb8e-bb6b9ba1a1c9'	System	28 Oct 2020 01:59:23
User entered '27 Oct 2020 20:56:38'	System	28 Oct 2020 01:59:23

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 15:03:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 15:03:52



US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 78'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-03T08:50:06', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '542d316d-24ef-4829-872c-2adfdecc3c44'	System	03 Nov 2020 14:53:38
User entered 'No (N)'	System	03 Nov 2020 14:53:38

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

Have you been exposed to someone with 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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-03T08:50:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '542d316d-24ef-4829-872c-2adfdecc3c44'	System	03 Nov 2020 14:53:38
User entered 'No (N)'	System	03 Nov 2020 14:53:38

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-03T08:50:52', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '542d316d-24ef-4829-872c-2adfdecc3c44'	System	03 Nov 2020 14:53:38
User entered '03 Nov 2020 08:50:52'	System	03 Nov 2020 14:53:38

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 15:03:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 15:03:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered 'Day 92'	System	20 Aug 2020 15:03:52

US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-17T09:32:42', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '258f7ba1-d57b-4852-aae3-593617182f0d'	System	17 Nov 2020 15:35:40
User entered 'No (N)'	System	17 Nov 2020 15:35:40



US3252261

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:33

Have you been exposed to someone with 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 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-17T09:32:48', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '258f7ba1-d57b-4852-aae3-593617182f0d'	System	17 Nov 2020 15:35:40
User entered 'No (N)'	System	17 Nov 2020 15:35:40

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-17T09:32:53', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '258f7ba1-d57b-4852-aae3-593617182f0d'	System	17 Nov 2020 15:35:40
User entered '17 Nov 2020 09:32:53'	System	17 Nov 2020 15:35:40

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 15:03:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:52:57
Data entry locked.	System	20 Aug 2020 15:03:52
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 15:03:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2020-11-21T15:03:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0ff0eb94-0240-4937-8e3d-7007c03a1d23'	System	21 Nov 2020 21:07:12
User entered 'No (N)'	System	21 Nov 2020 21:07:12

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-11-21T15:03:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0ff0eb94-0240-4937-8e3d-7007c03a1d23'	System	21 Nov 2020 21:07:12
User entered 'No (N)'	System	21 Nov 2020 21:07:12

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-21T15:04:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '0ff0eb94-0240-4937-8e3d-7007c03a1d23'	System	21 Nov 2020 21:07:12
User entered '21 Nov 2020 15:04:00'	System	21 Nov 2020 21:07:12



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2020-11-28T09:29:43', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1605d170-aa14-4bc2-a802-3809bb7f1f2c'	System	28 Nov 2020 15:33:11
User entered 'No (N)'	System	28 Nov 2020 15:33:11

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-11-28T09:29:53', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1605d170-aa14-4bc2-a802-3809bb7f1f2c'	System	28 Nov 2020 15:33:11
User entered 'No (N)'	System	28 Nov 2020 15:33:11

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-11-28T09:30:02', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1605d170-aa14-4bc2-a802-3809bb7f1f2c'	System	28 Nov 2020 15:33:11
User entered '28 Nov 2020 09:30:02'	System	28 Nov 2020 15:33:11

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2020-12-06T17:22:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b540384e-1ac6-4e95-a2ad-9400ba67be28'	System	06 Dec 2020 23:25:52
User entered 'No (N)'	System	06 Dec 2020 23:25:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-12-06T17:22:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b540384e-1ac6-4e95-a2ad-9400ba67be28'	System	06 Dec 2020 23:25:52
User entered 'No (N)'	System	06 Dec 2020 23:25:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-12-06T17:22:36', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'b540384e-1ac6-4e95-a2ad-9400ba67be28' User entered '06 Dec 2020 17:22:36'	System	06 Dec 2020 23:25:52
	System	06 Dec 2020 23:25:52

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2020-12-12T10:04:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '46dab257-d6f7-4bb9-b538-0e279c868eed'	System	12 Dec 2020 16:07:28
User entered 'No (N)'	System	12 Dec 2020 16:07:28



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-12-12T10:04:09', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '46dab257-d6f7-4bb9-b538-0e279c868eed'	System	12 Dec 2020 16:07:28
User entered 'No (N)'	System	12 Dec 2020 16:07:28

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-12-12T10:04:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '46dab257-d6f7-4bb9-b538-0e279c868eed'	System	12 Dec 2020 16:07:28
User entered '12 Dec 2020 10:04:13'	System	12 Dec 2020 16:07:28

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2020-12-19T00:29:32', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '29441710-47f2-4148-bb5e-73bab3ad6fc3'	System	19 Dec 2020 06:32:55
User entered 'No (N)'	System	19 Dec 2020 06:32:55

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-12-19T00:29:37', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '29441710-47f2-4148-bb5e-73bab3ad6fc3'	System	19 Dec 2020 06:32:55
User entered 'No (N)'	System	19 Dec 2020 06:32:55

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-12-19T00:29:41', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '29441710-47f2-4148-bb5e-73bab3ad6fc3' User entered '19 Dec 2020 00:29:41'	System	19 Dec 2020 06:32:55
	System	19 Dec 2020 06:32:55



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2020-12-26T12:45:12', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '67c06f62-ab95-493d-a9a7-562513146f57'	System	26 Dec 2020 18:48:37
User entered 'No (N)'	System	26 Dec 2020 18:48:37

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2020-12-26T12:45:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '67c06f62-ab95-493d-a9a7-562513146f57'	System	26 Dec 2020 18:48:37
User entered 'No (N)'	System	26 Dec 2020 18:48:37

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2020-12-26T12:45:20', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '67c06f62-ab95-493d-a9a7-562513146f57'	System	26 Dec 2020 18:48:37
User entered '26 Dec 2020 12:45:20'	System	26 Dec 2020 18:48:37

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-01-03T11:58:50', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cf60661d-198c-4210-8320-0f1ba0e7eb8b'	System	03 Jan 2021 18:02:13
User entered 'No (N)'	System	03 Jan 2021 18:02:13

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-01-03T11:58:54', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cf60661d-198c-4210-8320-0f1ba0e7eb8b'	System	03 Jan 2021 18:02:13
User entered 'No (N)'	System	03 Jan 2021 18:02:13

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-01-03T11:58:58', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'cf60661d-198c-4210-8320-0f1ba0e7eb8b'	System	03 Jan 2021 18:02:13
User entered '03 Jan 2021 11:58:58'	System	03 Jan 2021 18:02:13

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-01-09T00:23:06', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a9f69822-bca1-4762-9749-91e1ec41b383'	System	09 Jan 2021 06:26:28
User entered 'No (N)'	System	09 Jan 2021 06:26:28



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-01-09T00:23:11', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a9f69822-bca1-4762-9749-91e1ec41b383'	System	09 Jan 2021 06:26:28
User entered 'No (N)'	System	09 Jan 2021 06:26:28

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-01-09T00:23:15', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'a9f69822-bca1-4762-9749-91e1ec41b383'	System	09 Jan 2021 06:26:28
User entered '09 Jan 2021 00:23:15'	System	09 Jan 2021 06:26:28

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-01-16T01:55:10', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1febc409-b571-4838-9872-a9eb8b699e60'	System	16 Jan 2021 07:58:30
User entered 'No (N)'	System	16 Jan 2021 07:58:30

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-01-16T01:55:14', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1febc409-b571-4838-9872-a9eb8b699e60'	System	16 Jan 2021 07:58:30
User entered 'No (N)'	System	16 Jan 2021 07:58:30

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-01-16T01:55:18', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '1febc409-b571-4838-9872-a9eb8b699e60'	System	16 Jan 2021 07:58:30
User entered '16 Jan 2021 01:55:18'	System	16 Jan 2021 07:58:30



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-01-23T19:03:25', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5f1766d5-5093-4cfd-84c0-9c7870a7285e'	System	24 Jan 2021 01:06:44
User entered 'No (N)'	System	24 Jan 2021 01:06:44

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-01-23T19:03:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5f1766d5-5093-4cfd-84c0-9c7870a7285e'	System	24 Jan 2021 01:06:44
User entered 'No (N)'	System	24 Jan 2021 01:06:44

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-01-23T19:03:33', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5f1766d5-5093-4cfd-84c0-9c7870a7285e' User entered '23 Jan 2021 19:03:33'	System	24 Jan 2021 01:06:44

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-01-30T00:39:56', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3f23d0a3-b980-4dbb-b178-f0ed5c49b7b9'	System	30 Jan 2021 06:43:20
User entered 'No (N)'	System	30 Jan 2021 06:43:20

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-01-30T00:40:04', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3f23d0a3-b980-4dbb-b178-f0ed5c49b7b9'	System	30 Jan 2021 06:43:20
User entered 'No (N)'	System	30 Jan 2021 06:43:20

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-01-30T00:40:08', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '3f23d0a3-b980-4dbb-b178-f0ed5c49b7b9'	System	30 Jan 2021 06:43:20
User entered '30 Jan 2021 00:40:08'	System	30 Jan 2021 06:43:20

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-02-06T10:19:17', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd1bf3b3a-45b1-4c1a-aa78-d9e746d66c08'	System	06 Feb 2021 16:22:40
User entered 'No (N)'	System	06 Feb 2021 16:22:40



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-02-06T10:19:21', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd1bf3b3a-45b1-4c1a-aa78-d9e746d66c08'	System	06 Feb 2021 16:22:40
User entered 'No (N)'	System	06 Feb 2021 16:22:40

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-02-06T10:19:29', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd1bf3b3a-45b1-4c1a-aa78-d9e746d66c08'	System	06 Feb 2021 16:22:40
User entered '06 Feb 2021 10:19:29'	System	06 Feb 2021 16:22:40

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-02-13T14:17:02', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5b6a89fc-d80d-4c1f-bd77-dffdf3e777ae'	System	13 Feb 2021 20:20:25
User entered 'No (N)'	System	13 Feb 2021 20:20:25

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-02-13T14:17:07', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5b6a89fc-d80d-4c1f-bd77-dffdf3e777ae'	System	13 Feb 2021 20:20:25
User entered 'No (N)'	System	13 Feb 2021 20:20:25

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-02-13T14:17:13', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5b6a89fc-d80d-4c1f-bd77-dffdf3e777ae'	System	13 Feb 2021 20:20:25
User entered '13 Feb 2021 14:17:13'	System	13 Feb 2021 20:20:25



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-02-20T12:48:55', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '410e08e6-cd67-47f9-84c8-52fb1cbdb84b'	System	20 Feb 2021 18:52:20
User entered 'No (N)'	System	20 Feb 2021 18:52:20

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-02-20T12:49:03', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '410e08e6-cd67-47f9-84c8-52fb1cbdb84b'	System	20 Feb 2021 18:52:20
User entered 'No (N)'	System	20 Feb 2021 18:52:20

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-02-20T12:49:10', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '410e08e6-cd67-47f9-84c8-52fb1cbdb84b'	System	20 Feb 2021 18:52:20
User entered '20 Feb 2021 12:49:10'	System	20 Feb 2021 18:52:20

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-02-27T10:05:22-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd89ee3ad-0db6-4744-8f1b-89c65e83c227'	System	27 Feb 2021 16:09:33
User entered 'No (N)'	System	27 Feb 2021 16:09:33

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-02-27T10:05:27-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd89ee3ad-0db6-4744-8f1b-89c65e83c227'	System	27 Feb 2021 16:09:33
User entered 'No (N)'	System	27 Feb 2021 16:09:33

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-02-27T10:05:35-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'd89ee3ad-0db6-4744-8f1b-89c65e83c227'	System	27 Feb 2021 16:09:33
User entered '27 Feb 2021 10:05:35'	System	27 Feb 2021 16:09:33

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:33:16

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-03-06T00:45:26-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2d7c9171-6406-4e3e-8f82-e63d76816a75'	System	06 Mar 2021 06:49:49
User entered 'No (N)'	System	06 Mar 2021 06:49:49



**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-03-06T00:45:30-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2d7c9171-6406-4e3e-8f82-e63d76816a75'	System	06 Mar 2021 06:49:49
User entered 'No (N)'	System	06 Mar 2021 06:49:49

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-03-06T00:45:36-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '2d7c9171-6406-4e3e-8f82-e63d76816a75'	System	06 Mar 2021 06:49:49
User entered '06 Mar 2021 00:45:36'	System	06 Mar 2021 06:49:49

**US3252261**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-03-13T09:15:58-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '08ae57b0-2fad-464a-b8d5-1e639fd3ac2f' User entered 'No (N)'	System	13 Mar 2021 15:19:56
	System	13 Mar 2021 15:19:56

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-03-13T09:16:01-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '08ae57b0-2fad-464a-b8d5-1e639fd3ac2f' User entered 'No (N)'	System	13 Mar 2021 15:19:56
	System	13 Mar 2021 15:19:56

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-03-13T09:16:05-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '08ae57b0-2fad-464a-b8d5-1e639fd3ac2f' User entered '13 Mar 2021 09:16:05'	System	13 Mar 2021 15:19:56
	System	13 Mar 2021 15:19:56



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-03-22T11:53:35-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'c2d8dd48-c47b-4229-9fc1-f7f97b8eae11'	System	22 Mar 2021 17:11:09
User entered 'No (N)'	System	22 Mar 2021 17:11:09

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-03-22T11:53:39-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'c2d8dd48-c47b-4229-9fc1-f7f97b8eae11'	System	22 Mar 2021 17:11:09
User entered 'No (N)'	System	22 Mar 2021 17:11:09

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-03-22T11:53:46-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: 'c2d8dd48-c47b-4229-9fc1-f7f97b8eae11'	System	22 Mar 2021 17:11:09
User entered '22 Mar 2021 11:53:46'	System	22 Mar 2021 17:11:09

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-03-27T10:12:52-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7955b579-23b0-48ef-a6e2-74e628ecbd87'	System	27 Mar 2021 15:17:03
User entered 'No (N)'	System	27 Mar 2021 15:17:03

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-03-27T10:12:56-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7955b579-23b0-48ef-a6e2-74e628ecbd87'	System	27 Mar 2021 15:17:03
User entered 'No (N)'	System	27 Mar 2021 15:17:03

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-03-27T10:13:01-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '7955b579-23b0-48ef-a6e2-74e628ecbd87'	System	27 Mar 2021 15:17:03
User entered '27 Mar 2021 10:13:01'	System	27 Mar 2021 15:17:03

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-04-04T20:35:16-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '59c0852a-055f-4352-a265-1f2116e44ede' User entered 'No (N)'	System	05 Apr 2021 01:39:29
	System	05 Apr 2021 01:39:29



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-04-04T20:35:24-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '59c0852a-055f-4352-a265-1f2116e44ede' User entered 'No (N)'	System	05 Apr 2021 01:39:29

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-04-04T20:35:28-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '59c0852a-055f-4352-a265-1f2116e44ede' User entered '04 Apr 2021 20:35:28'	System	05 Apr 2021 01:39:29
	System	05 Apr 2021 01:39:29

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-04-10T00:06:14-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '251d79cd-1dc9-4e0f-8272-92210fdc49dc' User entered 'No (N)'	System	10 Apr 2021 05:10:25
	System	10 Apr 2021 05:10:25

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-04-10T00:06:17-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '251d79cd-1dc9-4e0f-8272-92210fdc49dc'	System	10 Apr 2021 05:10:25
User entered 'No (N)'	System	10 Apr 2021 05:10:25

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-04-10T00:06:20-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '251d79cd-1dc9-4e0f-8272-92210fdc49dc' User entered '10 Apr 2021 00:06:20'	System	10 Apr 2021 05:10:25
	System	10 Apr 2021 05:10:25



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-04-20T13:18:38-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58c3a459-0e11-49bd-b58e-e7ebf804ad3a' User entered 'No (N)'	System	20 Apr 2021 18:23:06

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-04-20T13:18:43-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58c3a459-0e11-49bd-b58e-e7ebf804ad3a' User entered 'No (N)'	System	20 Apr 2021 18:23:06

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-04-20T13:18:47-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '58c3a459-0e11-49bd-b58e-e7ebf804ad3a' User entered '20 Apr 2021 13:18:47'	System	20 Apr 2021 18:23:06
	System	20 Apr 2021 18:23:06

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-04-24T00:02:48-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9784e035-bea9-45c3-b7b0-aa3ebb4d96be' User entered 'No (N)'	System	24 Apr 2021 05:07:38
	System	24 Apr 2021 05:07:38

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-04-24T00:02:54-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9784e035-bea9-45c3-b7b0-aa3ebb4d96be' User entered 'No (N)'	System	24 Apr 2021 05:07:38

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-04-24T00:03:20-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '9784e035-bea9-45c3-b7b0-aa3ebb4d96be' User entered '24 Apr 2021 00:03:20'	System	24 Apr 2021 05:07:38
	System	24 Apr 2021 05:07:38

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[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 (907b134012dd7bd7)', Time: '2021-05-01T00:13:24-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5afd9a74-9b03-4885-94ea-7d3a4f78a2bf'	System	01 May 2021 05:27:28
User entered 'No (N)'	System	01 May 2021 05:27:28



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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Have you been exposed to someone with 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 (907b134012dd7bd7)', Time: '2021-05-01T00:13:27-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5afd9a74-9b03-4885-94ea-7d3a4f78a2bf'	System	01 May 2021 05:27:28
User entered 'No (N)'	System	01 May 2021 05:27:28

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-05-01T00:13:31-05:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '5afd9a74-9b03-4885-94ea-7d3a4f78a2bf'	System	01 May 2021 05:27:28
User entered '01 May 2021 00:13:31'	System	01 May 2021 05:27:28

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:33:16



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:33:16



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:33:16



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:33:16

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:33:16



**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:33:16

**US3252261**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:12:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:33:16
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:33:16

US3252261

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:12:33**

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 15:59:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-02-27T10:05:53-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '14326542-5d5c-42d5-9094-d173675247b2'	System	27 Feb 2021 16:09:57
User entered 'No (N)'	System	27 Feb 2021 16:09:57

**US3252261**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:59:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (907b134012dd7bd7)', Time: '2021-02-27T10:06:02-06:00', User OID: 'PatientReportedOutcome (US3252261)', ODM File OID: '14326542-5d5c-42d5-9094-d173675247b2' User entered '27 Feb 2021 10:06:02'	System	27 Feb 2021 16:09:57
	System	27 Feb 2021 16:09:57

**US3252261**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Nov 2020 02:56:44
	(b) (4)	

US3252261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '11 Nov 2020'	Nancy Torrence (b) (4)	12 Nov 2020 02:56:44
	(b) (4)	

US3252261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	12 Nov 2020 02:56:44
	(b) (4)	



US3252261

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Nancy Torrence (b) (4)	12 Nov 2020 02:56:44
	(b) (4)	

US3252261

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Nov 2020 02:56:49
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:22:43
User entered 'I'	System	12 Nov 2020 02:56:49

**US3252261**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	16 Dec 2020 05:52:06
	(b) (4)	

US3252261

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '15 Dec 2020'	Shannon Moyer (b) (4)	16 Dec 2020 05:52:06
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	16 Dec 2020 05:52:06
	(b) (4)	

**US3252261**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	16 Dec 2020 05:52:06
	(b) (4)	

US3252261

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	16 Dec 2020 05:52:11
	(b) (4)	



**US3252261**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered 'I'	System	16 Dec 2020 05:52:11

**US3252261**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 08:19:07

US3252261

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '14 Jan 2021'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 08:19:07

US3252261

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Contact Not Made (CONTACT NOT MADE)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 08:19:07

US3252261

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'left voice mail'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 08:19:07

US3252261

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 08:19:11

**US3252261**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered 'I'	System	05 Feb 2021 08:19:11

**US3252261**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 07:38:27



US3252261

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 11:14:44
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'safety call was done out of window. due to weather conditions it was difficult to get a hold of the patient' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 07:38:46
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Mar 2021 07:38:27
User entered '18 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 07:38:27

US3252261

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Mar 2021 07:38:27

**US3252261**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 07:38:27

US3252261

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 07:38:32

**US3252261**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered 'I'	System	05 Mar 2021 07:38:32

US3252261

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 02:55:44

US3252261

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered '15 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 02:55:44

US3252261

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Mar 2021 02:55:44



**US3252261**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered 'VISIT4'	System	16 Mar 2021 02:55:44

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:48:27

**US3252261**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered empty.	System	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:48:27



US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:48:27

**US3252261**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:12:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered empty.	System	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered empty.	System	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered empty.	System	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:48:27

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered empty.	System	30 Mar 2021 19:48:27



US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22

US3252261

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22

US3252261

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 02:55:51

US3252261

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 02:55:51

US3252261

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 02:56:06

US3252261

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered '15 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 02:56:06

US3252261

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered '07:29'	(b) (4), (b) (6)	16 Mar 2021 02:56:06

**US3252261**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered '15 Mar 2021 07:29'	System	16 Mar 2021 02:56:06



US3252261

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 02:56:12

US3252261

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:23:22
User entered 'I'	System	16 Mar 2021 02:56:12

**US3252261**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:53:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 02:48:05

US3252261

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:53:13
User entered '15 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 02:48:05

**US3252261**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:53:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Apr 2021 02:48:05

**US3252261**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:12:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:53:13
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 02:48:05

US3252261

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:53:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 02:48:12

**US3252261**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 02:48:12



US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:08
	(b) (4)	

US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '21 Jan 2021'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:08
	(b) (4)	

US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:33

[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 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:08
	(b) (4)	

**US3252261**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:12:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 06:59:08

US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '21 Jan 2021'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:23
	(b) (4)	

**US3252261**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:33**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:56:49

US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:23
	(b) (4)	

**US3252261**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:33**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:56:40
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:56:49



US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:33

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '21 Jan 2021'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:23
	(b) (4)	

US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mRNA-1273 (mRNA-1273)'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:23
	(b) (4)	

US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mRNA-1273 (mRNA-1273)'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:23
	(b) (4)	

US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mRNA-1273 (mRNA-1273)'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:23
	(b) (4)	

US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:23
	(b) (4)	

**US3252261**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:33**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User entered empty.	System	22 Jan 2021 06:59:23

**US3252261**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:12:33**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User entered empty.	System	22 Jan 2021 06:59:23

US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:51
	(b) (4)	



US3252261

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '21 Jan 2021'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:51
	(b) (4)	

**US3252261**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '09:45'	Shannon Moyer (b) (4)	22 Jan 2021 06:59:51
	(b) (4)	

**US3252261**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:12:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User entered '21 Jan 2021 09:45'	System	22 Jan 2021 06:59:51

US3252261

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:12:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	22 Jan 2021 07:00:03
	(b) (4)	

US3252261

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:12:33**

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '21 Jan 2021'	Shannon Moyer (b) (4)	22 Jan 2021 07:00:03
	(b) (4)	

US3252261

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:12:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '09:45'	Shannon Moyer (b) (4)	22 Jan 2021 07:00:03
	(b) (4)	

**US3252261**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:12:33**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:57:34
User entered '21 Jan 2021 09:45'	System	22 Jan 2021 07:00:03

US3252261

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:12:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:51:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:40:59
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:45:47



US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:33
Reviewed for Safety.		12 Nov 2020 19:39:41
User entered	System	12 Nov 2020 19:39:37
'USA-US108-2020-mRNA-1273-P301000017'		
User entered 'New'	(b) (4), (b) (6)	12 Nov 2020 19:39:37

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:34
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure, LLT: Heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:47:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:47:37
Data point term sent to Coder	System	11 Nov 2020 21:46:28
User entered 'Heart Failure'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:36
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 16:12:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:44
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:50
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:54
User entered '1 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:55
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:45:45



US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:57
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:30:59
User entered '3 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:31:01
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

Severity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:31:10
User closed query 'PV Query: Since the subject was hospitalized for the event of heart failure, appropriate severity grade should be grade 4 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).		25 Nov 2020 15:44:07
Query 'PV Query: Since the subject was hospitalized for the event of heart failure, appropriate severity grade should be grade 4 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'Severity grade has been updated appropriately. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 21:49:15
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:48:05
User opened query 'PV Query: Since the subject was hospitalized for the event of heart failure, appropriate severity grade should be grade 4 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).		20 Nov 2020 21:46:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:31:13
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:31:38
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:31:40
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45



**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:31:41
User entered 'I'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 16:12:33

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:32:00
User entered '1 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:32:29
User entered '3 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:32:31
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:32:32
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:32:34
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:32:35
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 16:12:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:32:37
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Relationship to IP is noted as "not applicable" in source.. Please note that Per CCGs, "not applicable" can only be selected if AE is prior to first dose.' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 05:46:27
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 05:46:24
Query 'Relationship to IP is noted as "not applicable" in source.. Please note that Per CCGs, "not applicable" can only be selected if AE is prior to first dose.' answered with 'Updated on source.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 19:53:08
User opened query 'Relationship to IP is noted as "not applicable" in source.. Please note that Per CCGs, "not applicable" can only be selected if AE is prior to first dose.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 21:34:09
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 09 Jun 2021 16:12:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:34:23
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	27 Dec 2020 21:33:56
User closed query 'Per source, None. Please review source to reconcile.' (Site from CRA).	(b) (4), (b) (6)	27 Dec 2020 21:33:53
Query 'Per source, None. Please review source to reconcile.' answered with 'Source has been modified to show not applicable.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 19:50:17
User opened query 'Per source, None. Please review source to reconcile.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 21:36:27
User closed query 'PV Query: As the last dose of study drug was given on 16 Sep 2020, please update the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 15:43:54
Query 'PV Query: As the last dose of study drug was given on 16 Sep 2020, please update the action taken from none to not applicable.' answered with 'Data has been updated' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 21:49:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 21:49:28
User opened query 'PV Query: As the last dose of study drug was given on 16 Sep 2020, please update the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:45:45
User entered 'None (NONE)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

None

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:40
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:42
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #14-16 start/stop dates were not during this AE timeframe. Please review and reconcile AE and CM start and stop dates as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 13:47:23
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #14-16 start/stop dates were not during this AE timeframe. Please review and reconcile AE and CM start and stop dates as appropriate or update action taken. ' answered with 'Concomitant medication start dates reviewed and updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 22:45:02
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #14-16 start/stop dates were not during this AE timeframe. Please review and reconcile AE and CM start and stop dates as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:32:25
User entered 'I'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:46
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

US3252261

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:36:57
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 18:23:29
User closed query 'The narrative for the SAE is not present in source for verification. Please review/reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 18:23:27
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 19:59:34
User closed query 'PV Query: Was a cause (or possible cause) for the heart failure identified?' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 19:59:33
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)	05 Feb 2021 19:59:31
Query 'PV Query: Was a cause (or possible cause) for the heart failure identified?' answered with 'no records available' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 07:07:10
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no medical records available' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 07:06:57
Query 'The narrative for the SAE is not present in source for verification. Please review/reconcile. ' answered with 'there is no section in source which reflects this information. this data is generated from the report which was available through data entered in AE, progress report etc' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 07:06:36
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 'unable to obtain,' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 07:01:26
User opened query 'The narrative for the SAE is not present in source for verification. Please review/reconcile. ' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 03:25:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:33

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 20:51:00
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)	20 Nov 2020 22:58:42
User opened query 'PV Query: Was a cause (or possible cause) for the heart failure identified?' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:46:33
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)	20 Nov 2020 21:46:27
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)	20 Nov 2020 21:46:20
User entered 'Patient admitted because of shortness of breath, she stayed in the hospital for 3 days and got released. We will request medical records.'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:45:45

**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 21:45:45

**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 21:45:45

**US3252261**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 21:45:45

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 16:12:33**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:51:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:49:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
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) (b) (4)	21 Aug 2020 14:51:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:51:22
Data point term sent to Coder	System	21 Aug 2020 14:50:35
User entered 'Metropolol'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Hypertension'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '50'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mg (mg)'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:46:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '9 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:46:11
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:50:22
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User entered '1'	System	21 Aug 2020 14:50:22

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User entered '1'	System	21 Aug 2020 14:50:22

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:35
User entered '804 (804)'	System	21 Aug 2020 14:50:22



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:52:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:52:24
Data point term sent to Coder	System	21 Aug 2020 14:51:39
User entered 'Simvastatin'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Hyperlipidemia'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '20'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mg (mg)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:02
	(b) (4)	

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:51:02



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:51:02

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:51:02

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTS SYNONYM: LOSARTAN/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:53:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:53:26
Data point term sent to Coder	System	21 Aug 2020 14:52:40
User entered 'Losartan/Hydrochlorothiazide'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Hypertension'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '100/25'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mg (mg)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:46:28
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '9 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:46:28
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:51:44
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User entered '1'	System	21 Aug 2020 14:51:44

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User entered '1'	System	21 Aug 2020 14:51:44

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:18:56
User entered '804 (804)'	System	21 Aug 2020 14:51:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
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)	21 Aug 2020 14:53:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	21 Aug 2020 14:52:42
Data point term sent to Coder User entered 'Amlodipine'	System Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Hypertension'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '10'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mg (mg)'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:46:51
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '9 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:46:51
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:52:27
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User entered '1'	System	21 Aug 2020 14:52:27

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User entered '1'	System	21 Aug 2020 14:52:27

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 11:19:07
User entered '804 (804)'	System	21 Aug 2020 14:52:27

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:16
Data point term sent to Coder	System	21 Aug 2020 14:53:45
User entered 'Levothyroxine'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Hypothyroidism'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '112'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:12:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:44:40
Query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' answered with 'Dose unit updated' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:36:49
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	30 Sep 2020 14:36:38
User opened query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:51:48
User entered 'Other (OTHER)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty; reason for change Data Entry Error	Uche Ehiemua (b) (4)	30 Sep 2020 14:36:38
User entered 'mcg'	(b) (4)	
	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:15
	(b) (4)	

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:53:15

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:53:15

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:53:15



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:54
Data point term sent to Coder	System	21 Aug 2020 14:54:47
User entered 'Montelukast'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Asthma'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '10'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mg (mg)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 1995'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:53:55
	(b) (4)	

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:53:55



**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:53:55

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:53:55

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:55:17
Data point term sent to Coder	System	21 Aug 2020 14:54:48
User entered 'Baby Asprin'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 11:46:44
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated as per query' (Site from DM).	Shannon Moyer (b) (4)	09 Feb 2021 07:52:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Feb 2021 07:52:17
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:07:15
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Heart Health'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '81'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mg (mg)'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2013'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:54:43
	(b) (4)	

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:54:43

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:54:43

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:54:43

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:57:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:57:17
Data point term sent to Coder	System	21 Aug 2020 14:55:53
User entered 'Pantoprazole'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Gastroesophageal reflux disease'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:55:31

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '40'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mg (mg)'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2020'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:55:31
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:55:31

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:55:31

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:55:31

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:57:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:57:18
Data point term sent to Coder	System	21 Aug 2020 14:56:54
User entered 'Cetirizine'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Seasonal allergy'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '10'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'mg (mg)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:08
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:56:08

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:56:08

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:56:08



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 11:39:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 11:39:38
Data point term sent to Coder	System	21 Aug 2020 14:56:56
User entered 'OTC Vitamin D'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'dietary supplement'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:12:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:45:23
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Dosage update as per patient.' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:38:35
User entered '5000' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	30 Sep 2020 14:38:18
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:52:29
User entered '1'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'TU (IU)' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	30 Sep 2020 14:38:18
User entered 'tablet (TABLET)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 14:56:49
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:56:49



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:56:49

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:56:49

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:12:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 11:39:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 11:39:38
Data point term sent to Coder	System	21 Aug 2020 15:05:26
Data point term sent to Coder	System	21 Aug 2020 15:02:17
User entered 'OTC Vitamin B12'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:12:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:04:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 15:04:27
User entered 'dietary supplement' reason for change: Shannon Moyer Data Entry Error	(b) (4)	21 Aug 2020 15:04:27
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:02:06
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '1'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'tablet (TABLET)'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 15:02:06
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:02:06

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:02:06

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:02:06

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 05:52:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 05:52:45
Data point term sent to Coder	System	21 Aug 2020 15:03:19
User entered 'OTC Multivitamin'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Dietary supplement'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '1'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'tablet (TABLET)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:04
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:03:04

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:03:04

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:03:04

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 18:11:24
Data point term sent to Coder	System	07 Dec 2020 17:48:29
Coding entries removed.	Joanna Gurrola Mahoney (b) (4)	07 Dec 2020 17:47:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:05:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:05:15
Data point term sent to Coder	System	21 Aug 2020 15:04:25
User entered 'Advair'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Asthma'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '230/21'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:46:15
Query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' answered with 'Dose unit updated.' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:40:08
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	30 Sep 2020 14:39:48
User opened query 'Per DM CLR: Dose Unit=Other; MCG. Please review and verify if the Dose Unit can be changed to ug as this is one of the pre-listed options in the Unit field. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:50:56
User entered 'Other (OTHER)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty; reason for change Data Entry Error	Uche Ehiemua (b) (4)	30 Sep 2020 14:39:48
User entered 'mcg'	(b) (4)	
	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:46:19
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'frequency updated as per patient' (Site from DM).	Uche Ehiemua (b) (4)	30 Sep 2020 14:40:43
User entered 'as needed (PRN)' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	30 Sep 2020 14:39:48
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 10:51:19
User entered 'once daily (QD)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:12:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 13:54:27
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'Route of medication updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	07 Dec 2020 17:48:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	07 Dec 2020 17:47:43
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:51:30
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'UN UNK 2005'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered '0'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered empty.	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User entered 'No (N)'	Shannon Moyer (b) (4)	21 Aug 2020 15:03:56
	(b) (4)	

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:39:48
User entered '1'	System	21 Aug 2020 15:03:56

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:39:48
User entered '1'	System	21 Aug 2020 15:03:56

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:39:48
User entered '804 (804)'	System	21 Aug 2020 15:03:56



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: OLMESARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:11:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:11:23
Data point term sent to Coder	System	07 Dec 2020 17:47:28
Coding entries removed.	Joanna Gurrola Mahoney (b) (4)	07 Dec 2020 17:47:13
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:58:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: OLMESARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:54:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:54:07
Data point term sent to Coder	System	11 Nov 2020 21:49:36
User entered 'Olmesartan'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:58:34
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Per source, the indication is Hypertension, but within source, this was given during the AE event of heart failure. ' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 03:25:44
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 03:25:43
Query 'Per source, the indication is Hypertension, but within source, this was given during the AE event of heart failure. ' answered with 'Indication updated as per source.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	07 Dec 2020 17:47:24
User entered 'hypertension' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	07 Dec 2020 17:47:13
User opened query 'Per source, the indication is Hypertension, but within source, this was given during the AE event of heart failure. ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 21:58:19
User entered 'Heart Failure'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:58:37
User entered '40'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:58:39
User entered 'mg (mg)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:58:40
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:58:57
User entered 'once daily (QD)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:58:58
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:59:00
User entered 'Oral (ORAL)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:59:01
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Per CDM: Please note, there is no AE that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 12:09:18
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:59:05
User entered '03 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 22:44:16
Query 'Per CDM: Please note, there is no AE that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' answered with 'AE has been recorded and matches the timeframe.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:03:47
User opened query 'Per CDM: Please note, there is no AE that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the AE eCRF as appropriate or, provide AE record number this indication pertains to. Thanks.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 10:58:05
User entered '9 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:59:15
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:59:19
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:01:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:12:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	27 Dec 2020 21:51:47
User closed query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:13:20
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	02 Dec 2020 23:27:47
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Dec 2020 23:27:39
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:30:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:03:12
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	24 Sep 2020 05:01:44

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:44



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	24 Sep 2020 05:01:44

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 21:48:48
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:47:53
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4)	(b) (4) 24 Sep 2020 05:01:44

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:01:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:50:36
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 Nov 2020 21:50:36
Data point term sent to Coder	System	11 Nov 2020 21:49:36
User entered 'Furosemide'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:01:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:02:22
User entered 'Heart Failure'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:02:26
User entered '20'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:02:59
User entered 'mg (mg)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:03:05
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:03:10
User entered 'once daily (QD)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:03:08
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:03:11
User entered 'Oral (ORAL)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:07:37
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:07:41
User entered '03 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 22:44:25
User entered '9 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:07:42
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:07:54
DataPoint Un-verified.		02 Dec 2020 22:07:47
DataPoint Verified.		02 Dec 2020 22:07:46
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:07:57
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:12:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 03:25:55
User closed query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:13:32
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	02 Dec 2020 23:28:05
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	02 Dec 2020 23:27:59
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:30:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:04:01
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:49:33

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:49:33

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:49:33

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 21:49:33

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:09:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:51:36
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 Nov 2020 21:51:36
Data point term sent to Coder	System	11 Nov 2020 21:50:37
User entered 'Carvedilol'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:09:46
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:09:50
User entered 'Heart Failure'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 18:25:38
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:07:51
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	26 Jan 2021 08:02:41
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	26 Jan 2021 08:02:35
User entered '12.5' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	26 Jan 2021 08:02:35
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 22:09:13
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:09:52
User entered '12'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05



US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:09:54
User entered 'mg (mg)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:09:55
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:10:00
User entered 'once daily (QD)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:10:08
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:10:11
User entered 'Oral (ORAL)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:10:12
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:10:14
User entered '03 Nov 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 22:44:34
User entered '9 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:10:15
User entered '0'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05



US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 13:40:49
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'the corresponding medication is used to provide heart health' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 05:25:21
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 09:04:20
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:10:17
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:10:22
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:12:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 03:26:02
User closed query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:08:25
Query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'Updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 19:41:31
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	04 Dec 2020 19:41:05
User opened query 'Per CDM: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 16:30:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:04:18
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:50:05

**US3252261**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:12:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 21:50:05

US3252261

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 16:12:33**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 18:27:28
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 14:48:49

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'USA-US108-2020-MRNA-1273-P301000017'	System	12 Nov 2020 19:39:37



**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Joel'	System	12 Nov 2020 19:39:37



US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Solis'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:11:51
User closed query 'Please update to correct street address.' (Site from CRA).		19 Mar 2021 21:11:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
Query 'Please update to correct street address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:02:41
User opened query 'Please update to correct street address.' (Site from CRA).		09 Feb 2021 18:24:16
DataPoint Un-verified.		09 Feb 2021 18:24:04
DataPoint Verified.		02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered '5201 N. 10th Street'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'Mcallen'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 19:39:51
User entered 'TX'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:11:54
User closed query 'Please update to the correct site postal code.' (Site from CRA).		19 Mar 2021 21:11:53
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
Query 'Please update to the correct site postal code.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:02:47
Un-reviewed for Safety.		24 Feb 2021 04:02:35
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 04:02:35
User opened query 'Please update to the correct site postal code.' (Site from CRA).		09 Feb 2021 18:24:31
DataPoint Un-verified.		09 Feb 2021 18:24:18
DataPoint Verified.		02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'carmpa'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		25 Nov 2020 15:44:26
User entered 'US'	System	12 Nov 2020 19:39:58

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 15:44:39
User entered '1'	System	12 Nov 2020 19:39:58

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'USA-US108-2020-MRNA-1273-P301000017'	System	12 Nov 2020 19:39:37



**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Joel'	System	12 Nov 2020 19:39:37



US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Solis'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:11:51
User closed query 'Please update to correct street address.' (Site from CRA).		19 Mar 2021 21:11:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
Query 'Please update to correct street address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:02:41
User opened query 'Please update to correct street address.' (Site from CRA).		09 Feb 2021 18:24:16
DataPoint Un-verified.		09 Feb 2021 18:24:04
DataPoint Verified.		02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered '5201 N. 10th Street'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Mcallen'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'TX'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:11:54
User closed query 'Please update to the correct site postal code.' (Site from CRA).		19 Mar 2021 21:11:53
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
Query 'Please update to the correct site postal code.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:02:47
Un-reviewed for Safety.		24 Feb 2021 04:02:35
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 04:02:35
User opened query 'Please update to the correct site postal code.' (Site from CRA).		09 Feb 2021 18:24:31
DataPoint Un-verified.		09 Feb 2021 18:24:18
DataPoint Verified.		02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'carmpa'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		25 Nov 2020 15:44:26
User entered 'US'	System	12 Nov 2020 19:39:58

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 15:44:39
User entered '1'	System	12 Nov 2020 19:39:58

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:12:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
User entered '12/Nov/2020 19:39'	System	12 Nov 2020 19:39:58



US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:12:33

**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.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		25 Nov 2020 15:44:26
User entered 'I'		12 Nov 2020 19:39:58

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'USA-US108-2020-MRNA-1273-P301000017'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Yes (Y)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37



**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'No (N)'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Joel'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Solis'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:11:51
User closed query 'Please update to correct street address.' (Site from CRA).		19 Mar 2021 21:11:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
Query 'Please update to correct street address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:02:41
User opened query 'Please update to correct street address.' (Site from CRA).		09 Feb 2021 18:24:16
DataPoint Un-verified.		09 Feb 2021 18:24:04
DataPoint Verified.		02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered '5201 N. 10th Street'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'Mcallen'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'TX'	System	12 Nov 2020 19:39:37

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:33

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:11:54
User closed query 'Please update to the correct site postal code.' (Site from CRA).		19 Mar 2021 21:11:53
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
Query 'Please update to the correct site postal code.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 04:02:47
Un-reviewed for Safety.		24 Feb 2021 04:02:35
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 04:02:35
User opened query 'Please update to the correct site postal code.' (Site from CRA).		09 Feb 2021 18:24:31
DataPoint Un-verified.		09 Feb 2021 18:24:18
DataPoint Verified.		02 Dec 2020 21:28:25
Reviewed for Safety.		12 Nov 2020 19:39:51
User entered 'carmpa'	System	12 Nov 2020 19:39:37

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
Reviewed for Safety.		25 Nov 2020 15:44:26
User entered 'US'	System	12 Nov 2020 19:39:58



**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:12:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Nov 2020 15:44:39
User entered '1'	System	12 Nov 2020 19:39:58

**US3252261**

**Folder: SAE USA-US108-2020-MRNA-1273-P301000017**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:12:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
User entered '25/Nov/2020 10:44'	System	25 Nov 2020 15:44:39

US3252261

Folder: SAE USA-US108-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:12:33

**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.	Joel Solis (b) (4)	05 Mar 2021 20:28:09
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 21:28:25
User entered 'I'		25 Nov 2020 15:44:39