

US3252665 (Prod: Centex Studies Inc)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:15:04

All time stamps listed in this document are displayed in GMT

US3252665

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

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[Participant ID](#)

US3252665

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

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US3252665

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	29
Age Units	YEARS
Age (Derived)	29
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 04:12:04

Generated On: 11 Aug 2021 22:15:04

Date of Informed Consent ( <i>dd MMM yyyy</i> )	14 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" 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 04:12:04

Generated On: 11 Aug 2021 22:15:04

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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 04:12:04

Generated On: 11 Aug 2021 22:15:04

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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 04:12:04

Generated On: 11 Aug 2021 22:15:04

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



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:27 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 13:27
Height ( <i>xxx.x</i> )	60 in
Weight ( <i>xxx.x</i> )	233.4 lb
BMI ( <i>xxx.x</i> )	45.67812 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 04:12:04

Generated On: 11 Aug 2021 22:15:04

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 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 04:12:04

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Date of assessment (*dd MMM yyyy*) 14 OCT 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	14 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 04:12:04

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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 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

What was the date of randomization? (dd MMM yyyy) 14 OCT 2020

What was the participant's randomization number? 147022

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 04:12:05

Generated On: 11 Aug 2021 22:15:04

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 04:12:05

Generated On: 11 Aug 2021 22:15:04

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)	14 OCT 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 13:27
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	14:59 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 14:59
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 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 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 OCT 2020

What was the treatment time? (00:00-23:59) 14:29 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 14:29

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 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 OCT 2020
Collection time (00:00-23:59)	14:21 (24 HR)
Collection date and time (derived)	14 OCT 2020 14:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Collection date ( <i>dd MMM yyyy</i> )			14 OCT 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:55	14 OCT 2020 13:55
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**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):

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

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

PC Time Stamp 14 OCT 2020 14:58

PC Open Date & Time 14 OCT 2020 14:49

PC Close Date & Time 14 OCT 2020 17:19

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**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):

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

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

PC Time Stamp 14 OCT 2020 18:25

PC Open Date & Time 14 OCT 2020 18:14

PC Close Date & Time 15 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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**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

96.9 °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

15 OCT 2020 20:50

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**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

97.1 °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 OCT 2020 23:56

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 23:26

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.7 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

18 OCT 2020 21:19

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PC Open Date & Time

18 OCT 2020 12:00

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PC Close Date & Time

19 OCT 2020 11:59

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US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

---

**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

19 OCT 2020 21:27

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59



US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 22:53

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**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

14 OCT 2020 14:59

PC Open Date & Time

14 OCT 2020 14:49

PC Close Date & Time

14 OCT 2020 17:19

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**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

14 OCT 2020 18:26

PC Open Date & Time

14 OCT 2020 18:14

PC Close Date & Time

15 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 20:58

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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

6

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

16 OCT 2020 23:56

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 23:26

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**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

18 OCT 2020 21:19

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 21:26

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59



US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 22:55

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**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 ☐

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 14:59
PC Open Date & Time	14 OCT 2020 14:49
PC Close Date & Time	14 OCT 2020 17:19

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**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 ☐

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 18:27
PC Open Date & Time	14 OCT 2020 18:14
PC Close Date & Time	15 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 20:59
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

		Yes <input type="checkbox"/>
PC Time stamp	16 OCT 2020 23:57	
PC Open Date & Time	16 OCT 2020 12:00	
PC Close Date & Time	17 OCT 2020 11:59	

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 23:27
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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 ☒

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 21:20
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
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US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 21:27
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 22:55
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3252665

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252665

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252665

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252665

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252665

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252665

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252665

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 10:22
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 11:28
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3252665

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

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.*

US3252665

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	11 NOV 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

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) 11 NOV 2020

What was the treatment time? (00:00-23:59) 10:58 (24 HR)

Treatment Date and Time (derived) 11 NOV 2020 10:58

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

US3252665

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 NOV 2020

Collection time (00:00-23:59)

10:50 (24 HR)

Collection date and time (derived)

11 NOV 2020 10:50

US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Collection date (dd MMM yyyy)			11 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:42	11 NOV 2020 10:42
Nasopharyngeal Swab 2	No		

US3252665

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 NOV 2020 11:29

PC Open Date & Time

11 NOV 2020 11:18

PC Close Date & Time

11 NOV 2020 13:48

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	11 NOV 2020 21:17
PC Open Date & Time	11 NOV 2020 14:43
PC Close Date & Time	12 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

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

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	12 NOV 2020 20:15
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**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

97.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

13 NOV 2020 22:51

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 NOV 2020 20:35

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 NOV 2020 22:47

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

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 NOV 2020 23:11

---

PC Open Date & Time

16 NOV 2020 12:00

---

PC Close Date & Time

17 NOV 2020 11:59

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US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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**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

96.9 °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

17 NOV 2020 22:14

---

PC Open Date & Time

17 NOV 2020 12:00

---

PC Close Date & Time

18 NOV 2020 11:59

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US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**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

11 NOV 2020 11:29

PC Open Date & Time

11 NOV 2020 11:18

PC Close Date & Time

11 NOV 2020 13:48

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

30

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 NOV 2020 21:21

PC Open Date & Time

11 NOV 2020 14:43

PC Close Date & Time

12 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**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)**

55

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)**

55

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

12 NOV 2020 20:18

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**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)**

70

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)**

70

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

13 NOV 2020 22:53

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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

30

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

14 NOV 2020 20:36

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 NOV 2020 22:48

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 NOV 2020 23:12

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 NOV 2020 22:15

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**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 ☐

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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

No ☒

Yes ☐

PC Time stamp	11 NOV 2020 11:30
PC Open Date & Time	11 NOV 2020 11:18
PC Close Date & Time	11 NOV 2020 13:48

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**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 ☐

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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

No ☒

Yes ☐

PC Time stamp	11 NOV 2020 21:21
PC Open Date & Time	11 NOV 2020 14:43
PC Close Date & Time	12 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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

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EAB) (1725)

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	13 NOV 2020 22:50
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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

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EAB) (1725)

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	14 NOV 2020 20:36
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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  
EAB) (1725)

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US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	15 NOV 2020 22:47
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	16 NOV 2020 23:11
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**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 ☒

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 22:15
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59



US3252665

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT

DAY 8

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

Yes ☐

No ☒

PC Time stamp

18 NOV 2020 22:53

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 NOV 2020 22:53

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

19 NOV 2020 13:42

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:15:04

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 NOV 2020 22:53
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:15:04

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 NOV 2020 13:42
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3252665

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3252665

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252665

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3252665

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252665

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252665

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 04:12:04

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252665

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	09:12 (24 HR)
Vital Signs Date and Time (derived)	9 DEC 2020 09:12
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	67 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

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.*

US3252665

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	9 DEC 2020
Collection time ( <i>00:00-23:59</i> )	09:35 (24 HR)
Collection date and time (derived)	9 DEC 2020 09:35

US3252665

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 04:12:05

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 61
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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2020 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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22 DEC 2020 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 21:27:07
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 06:30:59
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

08 JAN 2021 06:34:29

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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	15 JAN 2021 14:06:59
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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

24 JAN 2021 20:46:29

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 FEB 2021 21:19:21
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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

05 FEB 2021 07:36:42

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 12:18:15
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 05:14:14
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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

02 MAR 2021 08:17:27

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 07:12:38
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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

15 MAR 2021 13:46:13

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 MAR 2021 11:39:38

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	28 MAR 2021 12:11:03
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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06 APR 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 APR 2021 17:44:49
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 12:06:27

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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	23 APR 2021 08:20:29
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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

30 APR 2021 07:22:48

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 222

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

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

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

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

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

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

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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 <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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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01 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 OCT 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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28 DEC 2021 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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 <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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 APR 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

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19 APR 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

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26 APR 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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°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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

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03 MAY 2022 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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13 MAY 2022 00:01

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17 MAY 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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31 MAY 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2022 00:01

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07 JUN 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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="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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

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08 JUL 2022 00:01

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12 JUL 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

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22 JUL 2022 00:01

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26 JUL 2022 23:59



US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

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29 JUL 2022 00:01

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02 AUG 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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16 AUG 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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19 AUG 2022 00:01

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23 AUG 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

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06 SEP 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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09 SEP 2022 00:01

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13 SEP 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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16 SEP 2022 00:01

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20 SEP 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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18 OCT 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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15 NOV 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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22 NOV 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Close Date & Time](#)

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29 NOV 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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02 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

**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 ☐

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

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[Patient Cloud Open Date & Time](#)

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09 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2022 23:59

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US3252665

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:04

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

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

[Patient Cloud Open Date & Time](#)

16 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2022 23:59

US3252665

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:15:04

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		02 MAR 2021 08:17:44

US3252665

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3252665

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252665

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

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

US3252665

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252665

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:08:12

Generated On: 11 Aug 2021 22:15:04

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



US3252665

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:08:12

Generated On: 11 Aug 2021 22:15:04

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3252665**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:04**

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*

**US3252665**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:04**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252665

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:15:04

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"/>

**US3252665**

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

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

**Generated On: 11 Aug 2021 22:15:04**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3252665

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

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

US3252665

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:08:12

Generated On: 11 Aug 2021 22:15:04

Date of updated informed consent (*dd MMM yyyy*) 7 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*) 7 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 \_\_\_\_\_

US3252665

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00-23:59)	11:42 (24 HR)
Collection date and time (derived)	7 JAN 2021 11:42



US3252665

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	11:41
Collection Date and Time (derived)	7 JAN 2021 11:41

US3252665

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Apr 2021 21:08:11

Generated On: 11 Aug 2021 22:15:04

---

Did the participant experience any adverse events?

Yes ☐

No ☒

---

If Yes, enter details on the Adverse Events form.

---

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

---

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

Yes ☒

No ☐

---

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

---

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:08:12

Generated On: 11 Aug 2021 22:15:04

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication POLYCYSTIC OVARIAN SYNDROME

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:08:12

Generated On: 11 Aug 2021 22:15:04

	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)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:08:12

Generated On: 11 Aug 2021 22:15:04

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:08:12

Generated On: 11 Aug 2021 22:15:04

	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)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:08:12

Generated On: 11 Aug 2021 22:15:04

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:08:12

Generated On: 11 Aug 2021 22:15:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3252665

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 22:20:03

Generated On: 11 Aug 2021 22:15:04

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3252665

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:15:04

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

US3252665

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:15:04

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 ☐

Audit

US3252665 (Prod: Centex Studies Inc)

**US3252665**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:15:04**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'US3252665'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 18:33:34

US3252665

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:45:03

US3252665

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 18:33:36



US3252665

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Oct 2020 18:45:03

**US3252665**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:04**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'SCRN'	System	14 Oct 2020 18:45:03

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User closed query 'Per GCL Lab Reconciliation: Swab: For Datapoint "Sex" Female recorded in EDC however Missing in PPD Central lab. Also For Datapoint "Date of Birth" 1990 in EDC, however Missing in GCL . Please reconcile the data and update as needed. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 10:55:03
Query 'Per GCL Lab Reconciliation: Swab: For Datapoint "Sex" Female recorded in EDC however Missing in PPD Central lab. Also For Datapoint "Date of Birth" 1990 in EDC, however Missing in GCL . Please reconcile the data and update as needed. Else clarify, thank you. ' answered with 'Gender and YOB are both marked in Preclarus portal. We can not register a new patient without the YOB/Gender being inputted. If it is not inputted, it won't let us continue to the next page.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:48:06
User opened query 'Per GCL Lab Reconciliation: Swab: For Datapoint "Sex" Female recorded in EDC however Missing in PPD Central lab. Also For Datapoint "Date of Birth" 1990 in EDC, however Missing in GCL . Please reconcile the data and update as needed. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:06:31
User entered (b) (6) 1990'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 18:33:37

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '29'	(b) (4), (b) (6)	14 Oct 2020 18:45:16

**US3252665**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:15:04**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'YEARS'	System	14 Oct 2020 18:45:16

**US3252665**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:15:04**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered '29'	System	14 Oct 2020 18:45:30

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Female (F)'	(b) (4), (b) (6)	14 Oct 2020 18:45:16

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	14 Oct 2020 18:45:16



US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'I'	(b) (4), (b) (6)	14 Oct 2020 18:45:16

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:45:16

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:45:16

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:45:16

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:45:16

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:45:16

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:45:16

US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:45:16



US3252665

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:04

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 18:45:16

US3252665

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:04

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:45:30

US3252665

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:04

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'Oct 2020'	System	14 Oct 2020 18:45:30

US3252665

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:04

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered '2020'	System	14 Oct 2020 18:45:30

US3252665

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:04

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Amendment 4 (4)'	(b) (4), (b) (6)	14 Oct 2020 18:45:30

US3252665

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:04

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:45:30

US3252665

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:04

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:45:30

US3252665

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 18:45:30



**US3252665**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:15:04**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 18:45:30

US3252665

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	RWS_ENDPOINT	14 Oct 2020 18:33:36
	ENDPOINT (b) (4)	

US3252665

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:04

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'I'	System	14 Oct 2020 18:45:35

US3252665

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:15:04

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:45:35

US3252665

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:15:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 03:52:09
	(b) (4)	

US3252665

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Polycystic ovaries, LLT: Polycystic ovarian syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 03:55:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 03:55:32
Data point term sent to Coder	System	15 Oct 2020 03:54:26
User entered 'Polycystic Ovarian Syndrome'	Nancy Torrence (b) (4)	15 Oct 2020 03:54:05

US3252665

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:04

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'UN UNK 2018'	Nancy Torrence (b) (4)	15 Oct 2020 03:54:05
	(b) (4)	

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:54:05
	(b) (4)	



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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 03:54:05
	(b) (4)	

US3252665

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:54:05
	(b) (4)	

US3252665

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:54:05
	(b) (4)	

US3252665

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'Jan 2018'	System	15 Oct 2020 03:54:05

**US3252665**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered '2018'	System	15 Oct 2020 03:54:05

US3252665

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:04

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered empty.	System	15 Oct 2020 03:54:05

US3252665

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:04

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered empty.	System	15 Oct 2020 03:54:05

US3252665

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	



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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '13:27'	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	

**US3252665**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:04**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered '14 Oct 2020 13:27'	System	15 Oct 2020 03:56:09

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '60' in	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
DataPoint set to visible.	(b) (4) System	14 Oct 2020 18:45:35

US3252665

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '233.4' lb	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
DataPoint set to visible.	(b) (4) System	14 Oct 2020 18:45:35

US3252665

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered '45.67812'	System	15 Oct 2020 03:56:09
DataPoint set to visible.	System	14 Oct 2020 18:45:35

**US3252665**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:04**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'kg/m2'	System	15 Oct 2020 03:56:09
DataPoint set to visible.	System	14 Oct 2020 18:45:35

US3252665

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	



US3252665

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	

**US3252665**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:04**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'bpm'	System	15 Oct 2020 03:56:09

US3252665

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	

US3252665

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'breaths/min'	System	15 Oct 2020 03:56:09

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	

US3252665

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'mmHg'	System	15 Oct 2020 03:56:09



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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:09
	(b) (4)	

US3252665

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'mmHg'	System	15 Oct 2020 03:56:09

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11

US3252665

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 03:56:27
	(b) (4)	

US3252665

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Nancy Torrence (b) (4)	15 Oct 2020 03:56:27
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Nancy Torrence (b) (4)	15 Oct 2020 03:56:47
	(b) (4)	

US3252665

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:04

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 03:56:47
	(b) (4)	



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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:04

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:47
	(b) (4)	

US3252665

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:04

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:47
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:47
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:04

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:56:47
	(b) (4)	

US3252665

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:56:47
	(b) (4)	

US3252665

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:04

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:56:47
	(b) (4)	

US3252665

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 03:57:39
	(b) (4)	

US3252665

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Nancy Torrence (b) (4)	15 Oct 2020 03:57:39
	(b) (4)	



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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Urine (URINE)'	Nancy Torrence (b) (4)	15 Oct 2020 03:57:39
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Negative (NEGATIVE)'	Nancy Torrence (b) (4)	15 Oct 2020 03:57:39
	(b) (4)	

US3252665

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:57:39
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:57:39
	(b) (4)	

US3252665

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:57:39
	(b) (4)	

**US3252665**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:15:04**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered empty.	System	15 Oct 2020 03:57:39

US3252665

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

US3252665

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

US3252665

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

US3252665

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'I'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '0'	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

US3252665

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 03:58:59
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	14 Oct 2020 19:39:51

US3252665

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	14 Oct 2020 19:39:51

US3252665

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	14 Oct 2020 19:39:51

US3252665

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'VISIT1'	System	14 Oct 2020 19:39:51

US3252665

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 OCT 2020'	RWS_ENDPOINT	14 Oct 2020 18:43:34
	ENDPOINT (b) (4)	



US3252665

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:04

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '147022'	RWS_ENDPOINT	14 Oct 2020 18:43:34
	ENDPOINT (b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:04

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Oct 2020 18:43:34

US3252665

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:04

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:59:51
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:04

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:59:51
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:04

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 03:59:51
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:59:51
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:04

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:59:51
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:04

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 03:59:51
DataPoint set to visible.	(b) (4) System	14 Oct 2020 18:45:30



US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	15 Oct 2020 04:04:13

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '13:27'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '14 Oct 2020 13:27'	System	15 Oct 2020 04:04:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '98.3' F	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '71'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'bpm'	System	15 Oct 2020 04:04:13

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '18'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'breaths/min'	System	15 Oct 2020 04:04:13



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '124'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	15 Oct 2020 04:04:13

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '86'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	15 Oct 2020 04:04:13

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered missing code ND - Not Done.	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	15 Oct 2020 04:04:13

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14:59'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '14 Oct 2020 14:59'	System	15 Oct 2020 04:04:13

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '98.2' F	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '67'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'bpm'	System	15 Oct 2020 04:04:13



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '16'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'breaths/min'	System	15 Oct 2020 04:04:13

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '128'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	15 Oct 2020 04:04:13

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '85'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:13
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	15 Oct 2020 04:04:13

US3252665

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 04:04:44
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 04:04:44
	(b) (4)	



US3252665

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 04:05:21
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 04:05:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 04:05:21
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 04:05:21
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User closed query 'Per CDM: Data is required. If not performed, please update to "No".' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:15:45
Query 'Per CDM: Data is required. If not performed, please update to "No".' answered with 'updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:20:06
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:20:00
User opened query 'Per CDM: Data is required. If not performed, please update to "No".' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 21:00:02
User entered empty.	Nancy Torrence (b) (4) (b) (4)	15 Oct 2020 04:05:21

US3252665

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 04:05:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 04:05:21
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered empty.	System	15 Oct 2020 04:05:21



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	14 Oct 2020 19:39:38

US3252665

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Joanna Gurrola Mahoney (b) (4)	14 Oct 2020 19:39:38

US3252665

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Joanna Gurrola Mahoney (b) (4)	14 Oct 2020 19:39:38

US3252665

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 19:39:38

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	14 Oct 2020 19:39:38

US3252665

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14:29'	Joanna Gurrola Mahoney (b) (4)	14 Oct 2020 19:39:38

US3252665

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '14 Oct 2020 14:29'	System	14 Oct 2020 19:39:38

US3252665

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney (b) (4)	14 Oct 2020 19:39:38



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'ONCE'	System	14 Oct 2020 19:39:38

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 19:39:38

US3252665

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 04:06:44
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Nancy Torrence (b) (4)	15 Oct 2020 04:06:44
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14:21'	Nancy Torrence (b) (4)	15 Oct 2020 04:06:44
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '14 Oct 2020 14:21'	System	15 Oct 2020 04:06:44

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:15:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '14 Oct 2020'	Nancy Torrence (b) (4)	15 Oct 2020 04:07:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:15:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	15 Oct 2020 04:07:10



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:15:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 04:07:10
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:15:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '13:55'	Nancy Torrence (b) (4)	15 Oct 2020 04:07:10
	(b) (4)	

**US3252665**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '14 Oct 2020 13:55'	System	15 Oct 2020 04:07:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:15:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	15 Oct 2020 04:07:10

US3252665

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:15:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 04:07:10
	(b) (4)	

US3252665

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:15:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	15 Oct 2020 04:07:10
	(b) (4)	

**US3252665**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:15:04**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered empty.	System	15 Oct 2020 04:07:10

US3252665

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	15 Oct 2020 04:07:40
	(b) (4)	



US3252665

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '1'	System	15 Oct 2020 04:07:40

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:58:31', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bfb66ca2-3a75-40a6-85f6-6c0d2a039480'	System	14 Oct 2020 19:58:58
User entered 'Yes (Y)'	System	14 Oct 2020 19:58:58

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:58:35', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bfb66ca2-3a75-40a6-85f6-6c0d2a039480'	System	14 Oct 2020 19:58:58
User entered '98.2'	System	14 Oct 2020 19:58:58

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:58:44', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bfb66ca2-3a75-40a6-85f6-6c0d2a039480'	System	14 Oct 2020 19:58:58
User entered 'Yes (Y)'	System	14 Oct 2020 19:58:58

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted to confirm new medication details. Medication was added to concomitant medication list. Thank you. (Site from System).	(b) (4), (b) (6)	13 Nov 2020 13:31:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:07:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:58:50', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bfb66ca2-3a75-40a6-85f6-6c0d2a039480'	System	14 Oct 2020 19:58:58
User entered '1'	System	14 Oct 2020 19:58:58

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:58:50', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bfb66ca2-3a75-40a6-85f6-6c0d2a039480' User entered '0'	System	14 Oct 2020 19:58:58
	System	14 Oct 2020 19:58:58

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:58:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bfb66ca2-3a75-40a6-85f6-6c0d2a039480'	System	14 Oct 2020 19:58:58
User entered '14 Oct 2020 14:58'	System	14 Oct 2020 19:58:58



US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '14 Oct 2020 14:49'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '14 Oct 2020 17:19'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:25:17', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b5df9bde-adba-47e9-b710-abedddd3b9aa'	System	14 Oct 2020 23:26:00
User entered 'Yes (Y)'	System	14 Oct 2020 23:26:00

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:25:26', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b5df9bde-adba-47e9-b710-abedddd3b9aa'	System	14 Oct 2020 23:26:00
User entered '97.2'	System	14 Oct 2020 23:26:00

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:25:44', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b5df9bde-adba-47e9-b710-abedddd3b9aa'	System	14 Oct 2020 23:26:00
User entered 'Yes (Y)'	System	14 Oct 2020 23:26:00

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted to confirm new medication details. Medication was added to concomitant medication list. Thank you. (Site from System).	(b) (4), (b) (6)	13 Nov 2020 13:31:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:07:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:25:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b5df9bde-adba-47e9-b710-abadddd3b9aa'	System	14 Oct 2020 23:26:00
User entered '1'	System	14 Oct 2020 23:26:00

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:25:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b5df9bde-adba-47e9-b710-abadddd3b9aa'	System	14 Oct 2020 23:26:00
User entered '0'	System	14 Oct 2020 23:26:00



US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:25:53', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b5df9bde-adba-47e9-b710-abadddd3b9aa'	System	14 Oct 2020 23:26:00
User entered '14 Oct 2020 18:25'	System	14 Oct 2020 23:26:00

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '14 Oct 2020 18:14'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 2'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:50:50', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'fca0bf4f-fd89-43a4-93ae-63f0f088a438'	System	16 Oct 2020 01:51:01
User entered 'Yes (Y)'	System	16 Oct 2020 01:51:01

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:50:53', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'fca0bf4f-fd89-43a4-93ae-63f0f088a438'	System	16 Oct 2020 01:51:01
User entered '96.9'	System	16 Oct 2020 01:51:01

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:50:55', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'fca0bf4f-fd89-43a4-93ae-63f0f088a438'	System	16 Oct 2020 01:51:01
User entered 'No (N)'	System	16 Oct 2020 01:51:01

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:50:58', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'fca0bf4f-fd89-43a4-93ae-63f0f088a438'	System	16 Oct 2020 01:51:01
User entered '15 Oct 2020 20:50'	System	16 Oct 2020 01:51:01



US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 3'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '336913f7-f72b-4d70-8fd0-0dbdd5efa928'	System	17 Oct 2020 04:56:19
User entered 'Yes (Y)'	System	17 Oct 2020 04:56:19

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:10', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '336913f7-f72b-4d70-8fd0-0dbdd5efa928' User entered '97.1'	System	17 Oct 2020 04:56:19
	System	17 Oct 2020 04:56:19

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:14', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '336913f7-f72b-4d70-8fd0-0dbdd5efa928'	System	17 Oct 2020 04:56:19
User entered 'No (N)'	System	17 Oct 2020 04:56:19

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:16', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '336913f7-f72b-4d70-8fd0-0dbdd5efa928'	System	17 Oct 2020 04:56:19
User entered '16 Oct 2020 23:56'	System	17 Oct 2020 04:56:19

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 4'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:21', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9cce7ee5-c3f9-43f2-bb17-ad1fa219c843'	System	18 Oct 2020 04:26:35
User entered 'Yes (Y)'	System	18 Oct 2020 04:26:35

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:27', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9cce7ee5-c3f9-43f2-bb17-ad1fa219c843'	System	18 Oct 2020 04:26:35
User entered '97.0'	System	18 Oct 2020 04:26:35

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:29', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9cce7ee5-c3f9-43f2-bb17-ad1fa219c843'	System	18 Oct 2020 04:26:35
User entered 'No (N)'	System	18 Oct 2020 04:26:35

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:32', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9cce7ee5-c3f9-43f2-bb17-ad1fa219c843'	System	18 Oct 2020 04:26:35
User entered '17 Oct 2020 23:26'	System	18 Oct 2020 04:26:35

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 5'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:17:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8dafec4c-6af9-4956-9fc2-a7d88c623b1f'	System	19 Oct 2020 02:19:24
User entered 'Yes (Y)'	System	19 Oct 2020 02:19:24

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:13', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8dafec4c-6af9-4956-9fc2-a7d88c623b1f' User entered '96.7'	System	19 Oct 2020 02:19:24
	System	19 Oct 2020 02:19:24

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:15', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8dafec4c-6af9-4956-9fc2-a7d88c623b1f'	System	19 Oct 2020 02:19:24
User entered 'No (N)'	System	19 Oct 2020 02:19:24

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:17', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8dafec4c-6af9-4956-9fc2-a7d88c623b1f' User entered '18 Oct 2020 21:19'	System	19 Oct 2020 02:19:24
	System	19 Oct 2020 02:19:24

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 6'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:27:21', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b596614e-1e0f-40cf-9b35-90492198336d'	System	20 Oct 2020 02:27:32
User entered 'Yes (Y)'	System	20 Oct 2020 02:27:32

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:27:23', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b596614e-1e0f-40cf-9b35-90492198336d' User entered '97.0'	System	20 Oct 2020 02:27:32
	System	20 Oct 2020 02:27:32

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:27:25', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b596614e-1e0f-40cf-9b35-90492198336d'	System	20 Oct 2020 02:27:32
User entered 'No (N)'	System	20 Oct 2020 02:27:32

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:27:28', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b596614e-1e0f-40cf-9b35-90492198336d'	System	20 Oct 2020 02:27:32
User entered '19 Oct 2020 21:27'	System	20 Oct 2020 02:27:32

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 7'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:53:26', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1757be0d-ae25-43c7-97b2-081ed00dd560'	System	21 Oct 2020 03:53:43
User entered 'Yes (Y)'	System	21 Oct 2020 03:53:43



US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:53:28', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1757be0d-ae25-43c7-97b2-081ed00dd560'	System	21 Oct 2020 03:53:43
User entered '97.4'	System	21 Oct 2020 03:53:43

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:53:30', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1757be0d-ae25-43c7-97b2-081ed00dd560'	System	21 Oct 2020 03:53:43
User entered 'No (N)'	System	21 Oct 2020 03:53:43

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:53:39', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1757be0d-ae25-43c7-97b2-081ed00dd560'	System	21 Oct 2020 03:53:43
User entered '20 Oct 2020 22:53'	System	21 Oct 2020 03:53:43

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:03', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '78a2dcf6-93e7-4014-b072-544797aa4a9c'	System	14 Oct 2020 19:59:29
User entered 'None (1)'	System	14 Oct 2020 19:59:29

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:07', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '78a2dcf6-93e7-4014-b072-544797aa4a9c'	System	14 Oct 2020 19:59:29
User entered 'No (N)'	System	14 Oct 2020 19:59:29



US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:13', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '78a2dcf6-93e7-4014-b072-544797aa4a9c'	System	14 Oct 2020 19:59:29
User entered 'No (N)'	System	14 Oct 2020 19:59:29

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:21', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '78a2dcf6-93e7-4014-b072-544797aa4a9c'	System	14 Oct 2020 19:59:29
User entered 'None (1)'	System	14 Oct 2020 19:59:29

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:24', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '78a2dcf6-93e7-4014-b072-544797aa4a9c'	System	14 Oct 2020 19:59:29
User entered '14 Oct 2020 14:59'	System	14 Oct 2020 19:59:29

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '14 Oct 2020 14:49'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '14 Oct 2020 17:19'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:25:57', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '467725ed-b0bf-4b64-a894-4a2f0fa239d5'	System	14 Oct 2020 23:26:46
User entered 'None (1)'	System	14 Oct 2020 23:26:46

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:26:09', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '467725ed-b0bf-4b64-a894-4a2f0fa239d5'	System	14 Oct 2020 23:26:46
User entered 'No (N)'	System	14 Oct 2020 23:26:46



US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:26:31', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '467725ed-b0bf-4b64-a894-4a2f0fa239d5'	System	14 Oct 2020 23:26:46
User entered 'No (N)'	System	14 Oct 2020 23:26:46

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:26:38', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '467725ed-b0bf-4b64-a894-4a2f0fa239d5'	System	14 Oct 2020 23:26:46
User entered 'None (1)'	System	14 Oct 2020 23:26:46

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:26:42', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '467725ed-b0bf-4b64-a894-4a2f0fa239d5'	System	14 Oct 2020 23:26:46
User entered '14 Oct 2020 18:26'	System	14 Oct 2020 23:26:46

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '14 Oct 2020 18:14'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 2'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:51:11', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '49f6eb9f-e4e4-415a-8c5a-fd0c01c499d4'	System	16 Oct 2020 01:59:02
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 01:59:02

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:51:28', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '49f6eb9f-e4e4-415a-8c5a-fd0c01c499d4'	System	16 Oct 2020 01:59:02
User entered 'No (N)'	System	16 Oct 2020 01:59:02



US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:51:31', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '49f6eb9f-e4e4-415a-8c5a-fd0c01c499d4'	System	16 Oct 2020 01:59:02
User entered 'Yes (Y)'	System	16 Oct 2020 01:59:02

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:58:41', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '49f6eb9f-e4e4-415a-8c5a-fd0c01c499d4'	System	16 Oct 2020 01:59:02
User entered '20'	System	16 Oct 2020 01:59:02

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:58:53', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '49f6eb9f-e4e4-415a-8c5a-fd0c01c499d4'	System	16 Oct 2020 01:59:02
User entered 'None (1)'	System	16 Oct 2020 01:59:02

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:58:57', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '49f6eb9f-e4e4-415a-8c5a-fd0c01c499d4'	System	16 Oct 2020 01:59:02
User entered '15 Oct 2020 20:58'	System	16 Oct 2020 01:59:02

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 3'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:21', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f83867f9-ecf8-4e01-910e-54e0782aa078'	System	17 Oct 2020 04:56:58
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 04:56:58



US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:24', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f83867f9-ecf8-4e01-910e-54e0782aa078'	System	17 Oct 2020 04:56:58
User entered 'No (N)'	System	17 Oct 2020 04:56:58

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:28', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f83867f9-ecf8-4e01-910e-54e0782aa078'	System	17 Oct 2020 04:56:58
User entered 'Yes (Y)'	System	17 Oct 2020 04:56:58

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:41', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f83867f9-ecf8-4e01-910e-54e0782aa078'	System	17 Oct 2020 04:56:58
User entered '6'	System	17 Oct 2020 04:56:58

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:44', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f83867f9-ecf8-4e01-910e-54e0782aa078'	System	17 Oct 2020 04:56:58
User entered 'None (1)'	System	17 Oct 2020 04:56:58

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:55', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f83867f9-ecf8-4e01-910e-54e0782aa078'	System	17 Oct 2020 04:56:58
User entered '16 Oct 2020 23:56'	System	17 Oct 2020 04:56:58

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 4'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:36', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8fdb0806-775e-4e89-a5dc-4e5736690c10'	System	18 Oct 2020 04:26:55
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 04:26:55

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:39', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8fdb0806-775e-4e89-a5dc-4e5736690c10'	System	18 Oct 2020 04:26:55
User entered 'No (N)'	System	18 Oct 2020 04:26:55

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:46', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8fdb0806-775e-4e89-a5dc-4e5736690c10'	System	18 Oct 2020 04:26:55
User entered 'No (N)'	System	18 Oct 2020 04:26:55

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8fdb0806-775e-4e89-a5dc-4e5736690c10'	System	18 Oct 2020 04:26:55
User entered 'None (1)'	System	18 Oct 2020 04:26:55

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:52', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8fdb0806-775e-4e89-a5dc-4e5736690c10'	System	18 Oct 2020 04:26:55
User entered '17 Oct 2020 23:26'	System	18 Oct 2020 04:26:55

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 5'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:33', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b7d28753-1618-455d-8773-2e8c4620bc83'	System	19 Oct 2020 02:19:51
User entered 'Does not interfere with activity (2)'	System	19 Oct 2020 02:19:51

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:36', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b7d28753-1618-455d-8773-2e8c4620bc83'	System	19 Oct 2020 02:19:51
User entered 'No (N)'	System	19 Oct 2020 02:19:51

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:39', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b7d28753-1618-455d-8773-2e8c4620bc83'	System	19 Oct 2020 02:19:51
User entered 'No (N)'	System	19 Oct 2020 02:19:51

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:43', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b7d28753-1618-455d-8773-2e8c4620bc83'	System	19 Oct 2020 02:19:51
User entered 'None (1)'	System	19 Oct 2020 02:19:51

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:45', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b7d28753-1618-455d-8773-2e8c4620bc83'	System	19 Oct 2020 02:19:51
User entered '18 Oct 2020 21:19'	System	19 Oct 2020 02:19:51

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 6'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:26:44', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9e515942-1c0b-434e-a6ba-4c005d92f140'	System	20 Oct 2020 02:26:54
User entered 'None (1)'	System	20 Oct 2020 02:26:54

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:26:45', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9e515942-1c0b-434e-a6ba-4c005d92f140'	System	20 Oct 2020 02:26:54
User entered 'No (N)'	System	20 Oct 2020 02:26:54

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:26:47', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9e515942-1c0b-434e-a6ba-4c005d92f140'	System	20 Oct 2020 02:26:54
User entered 'No (N)'	System	20 Oct 2020 02:26:54

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:26:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9e515942-1c0b-434e-a6ba-4c005d92f140'	System	20 Oct 2020 02:26:54
User entered 'None (1)'	System	20 Oct 2020 02:26:54

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:26:51', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9e515942-1c0b-434e-a6ba-4c005d92f140'	System	20 Oct 2020 02:26:54
User entered '19 Oct 2020 21:26'	System	20 Oct 2020 02:26:54

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 7'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:54:37', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a3e98d92-8e6c-4dc3-a9db-ad61bdd564e4'	System	21 Oct 2020 03:55:27
User entered 'None (1)'	System	21 Oct 2020 03:55:27

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:54:40', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a3e98d92-8e6c-4dc3-a9db-ad61bdd564e4'	System	21 Oct 2020 03:55:27
User entered 'No (N)'	System	21 Oct 2020 03:55:27

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:54:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a3e98d92-8e6c-4dc3-a9db-ad61bdd564e4'	System	21 Oct 2020 03:55:27
User entered 'No (N)'	System	21 Oct 2020 03:55:27

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:19', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a3e98d92-8e6c-4dc3-a9db-ad61bdd564e4'	System	21 Oct 2020 03:55:27
User entered 'None (1)'	System	21 Oct 2020 03:55:27

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:24', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a3e98d92-8e6c-4dc3-a9db-ad61bdd564e4'	System	21 Oct 2020 03:55:27
User entered '20 Oct 2020 22:55'	System	21 Oct 2020 03:55:27

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:31', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e23b3281-c8f6-46e8-a1ca-6b2984021e6a'	System	14 Oct 2020 19:59:55
User entered 'None (0)'	System	14 Oct 2020 19:59:55

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:35', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e23b3281-c8f6-46e8-a1ca-6b2984021e6a'	System	14 Oct 2020 19:59:55
User entered 'None (0)'	System	14 Oct 2020 19:59:55

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:38', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e23b3281-c8f6-46e8-a1ca-6b2984021e6a'	System	14 Oct 2020 19:59:55
User entered 'None (0)'	System	14 Oct 2020 19:59:55

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:41', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e23b3281-c8f6-46e8-a1ca-6b2984021e6a'	System	14 Oct 2020 19:59:55
User entered 'None (0)'	System	14 Oct 2020 19:59:55

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:43', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e23b3281-c8f6-46e8-a1ca-6b2984021e6a'	System	14 Oct 2020 19:59:55
User entered 'None (0)'	System	14 Oct 2020 19:59:55

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:45', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e23b3281-c8f6-46e8-a1ca-6b2984021e6a'	System	14 Oct 2020 19:59:55
User entered 'None (0)'	System	14 Oct 2020 19:59:55

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e23b3281-c8f6-46e8-a1ca-6b2984021e6a'	System	14 Oct 2020 19:59:55
User entered 'No (N)'	System	14 Oct 2020 19:59:55

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T14:59:51', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e23b3281-c8f6-46e8-a1ca-6b2984021e6a'	System	14 Oct 2020 19:59:55
User entered '14 Oct 2020 14:59'	System	14 Oct 2020 19:59:55



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '14 Oct 2020 14:49'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '14 Oct 2020 17:19'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:26:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ab59281f-b526-43e7-b435-ec8fd7fd579e'	System	14 Oct 2020 23:27:11
User entered 'None (0)'	System	14 Oct 2020 23:27:11

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:26:52', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ab59281f-b526-43e7-b435-ec8fd7fd579e'	System	14 Oct 2020 23:27:11
User entered 'None (0)'	System	14 Oct 2020 23:27:11

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:26:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ab59281f-b526-43e7-b435-ec8fd7fd579e'	System	14 Oct 2020 23:27:11
User entered 'None (0)'	System	14 Oct 2020 23:27:11

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:26:56', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ab59281f-b526-43e7-b435-ec8fd7fd579e'	System	14 Oct 2020 23:27:11
User entered 'None (0)'	System	14 Oct 2020 23:27:11

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:26:58', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ab59281f-b526-43e7-b435-ec8fd7fd579e'	System	14 Oct 2020 23:27:11
User entered 'None (0)'	System	14 Oct 2020 23:27:11



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:27:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ab59281f-b526-43e7-b435-ec8fd7fd579e'	System	14 Oct 2020 23:27:11
User entered 'None (0)'	System	14 Oct 2020 23:27:11

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:27:04', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ab59281f-b526-43e7-b435-ec8fd7fd579e'	System	14 Oct 2020 23:27:11
User entered 'No (N)'	System	14 Oct 2020 23:27:11

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-14T18:27:06', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ab59281f-b526-43e7-b435-ec8fd7fd579e'	System	14 Oct 2020 23:27:11
User entered '14 Oct 2020 18:27'	System	14 Oct 2020 23:27:11

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '14 Oct 2020 18:14'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 2'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:59:02', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '53022bef-84be-4528-b344-e3bdcc2dce19'	System	16 Oct 2020 01:59:22
User entered 'None (0)'	System	16 Oct 2020 01:59:22

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:59:04', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '53022bef-84be-4528-b344-e3bdcc2dce19'	System	16 Oct 2020 01:59:22
User entered 'None (0)'	System	16 Oct 2020 01:59:22



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:59:06', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '53022bef-84be-4528-b344-e3bdcc2dce19'	System	16 Oct 2020 01:59:22
User entered 'None (0)'	System	16 Oct 2020 01:59:22

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:59:09', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '53022bef-84be-4528-b344-e3bdcc2dce19'	System	16 Oct 2020 01:59:22
User entered 'None (0)'	System	16 Oct 2020 01:59:22

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:59:11', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '53022bef-84be-4528-b344-e3bdcc2dce19'	System	16 Oct 2020 01:59:22
User entered 'None (0)'	System	16 Oct 2020 01:59:22

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:59:13', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '53022bef-84be-4528-b344-e3bdcc2dce19'	System	16 Oct 2020 01:59:22
User entered 'None (0)'	System	16 Oct 2020 01:59:22

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:59:15', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '53022bef-84be-4528-b344-e3bdcc2dce19'	System	16 Oct 2020 01:59:22
User entered 'No (N)'	System	16 Oct 2020 01:59:22

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-15T20:59:18', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '53022bef-84be-4528-b344-e3bdcc2dce19'	System	16 Oct 2020 01:59:22
User entered '15 Oct 2020 20:59'	System	16 Oct 2020 01:59:22

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 3'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:56:58', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b2509ec1-260e-4ddd-8ed0-e6f5c0b08dfa'	System	17 Oct 2020 04:57:16
User entered 'None (0)'	System	17 Oct 2020 04:57:16

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:57:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b2509ec1-260e-4ddd-8ed0-e6f5c0b08dfa'	System	17 Oct 2020 04:57:16
User entered 'None (0)'	System	17 Oct 2020 04:57:16

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:57:03', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b2509ec1-260e-4ddd-8ed0-e6f5c0b08dfa'	System	17 Oct 2020 04:57:16
User entered 'None (0)'	System	17 Oct 2020 04:57:16

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:57:04', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b2509ec1-260e-4ddd-8ed0-e6f5c0b08dfa'	System	17 Oct 2020 04:57:16
User entered 'None (0)'	System	17 Oct 2020 04:57:16

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:57:06', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b2509ec1-260e-4ddd-8ed0-e6f5c0b08dfa'	System	17 Oct 2020 04:57:16
User entered 'None (0)'	System	17 Oct 2020 04:57:16

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:57:07', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b2509ec1-260e-4ddd-8ed0-e6f5c0b08dfa'	System	17 Oct 2020 04:57:16
User entered 'None (0)'	System	17 Oct 2020 04:57:16

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:57:09', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b2509ec1-260e-4ddd-8ed0-e6f5c0b08dfa'	System	17 Oct 2020 04:57:16
User entered 'No (N)'	System	17 Oct 2020 04:57:16



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-16T23:57:11', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b2509ec1-260e-4ddd-8ed0-e6f5c0b08dfa'	System	17 Oct 2020 04:57:16
User entered '16 Oct 2020 23:57'	System	17 Oct 2020 04:57:16

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 4'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:55', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c6641205-5b95-42a5-a219-6827369c6133'	System	18 Oct 2020 04:27:17
User entered 'None (0)'	System	18 Oct 2020 04:27:17

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:26:58', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c6641205-5b95-42a5-a219-6827369c6133'	System	18 Oct 2020 04:27:17
User entered 'None (0)'	System	18 Oct 2020 04:27:17

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:27:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c6641205-5b95-42a5-a219-6827369c6133'	System	18 Oct 2020 04:27:17
User entered 'None (0)'	System	18 Oct 2020 04:27:17

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:27:02', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c6641205-5b95-42a5-a219-6827369c6133'	System	18 Oct 2020 04:27:17
User entered 'None (0)'	System	18 Oct 2020 04:27:17



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:27:04', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c6641205-5b95-42a5-a219-6827369c6133'	System	18 Oct 2020 04:27:17
User entered 'None (0)'	System	18 Oct 2020 04:27:17

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:27:06', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c6641205-5b95-42a5-a219-6827369c6133'	System	18 Oct 2020 04:27:17
User entered 'None (0)'	System	18 Oct 2020 04:27:17

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:27:12', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c6641205-5b95-42a5-a219-6827369c6133'	System	18 Oct 2020 04:27:17
User entered 'No (N)'	System	18 Oct 2020 04:27:17

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-17T23:27:14', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c6641205-5b95-42a5-a219-6827369c6133'	System	18 Oct 2020 04:27:17
User entered '17 Oct 2020 23:27'	System	18 Oct 2020 04:27:17

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 5'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:48', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ccad414-b9f0-4722-ada7-1db86b751b3b'	System	19 Oct 2020 02:20:06
User entered 'None (0)'	System	19 Oct 2020 02:20:06



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:51', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ccad414-b9f0-4722-ada7-1db86b751b3b'	System	19 Oct 2020 02:20:06
User entered 'None (0)'	System	19 Oct 2020 02:20:06

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:52', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ccad414-b9f0-4722-ada7-1db86b751b3b'	System	19 Oct 2020 02:20:06
User entered 'None (0)'	System	19 Oct 2020 02:20:06

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ccad414-b9f0-4722-ada7-1db86b751b3b'	System	19 Oct 2020 02:20:06
User entered 'None (0)'	System	19 Oct 2020 02:20:06

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:55', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ccad414-b9f0-4722-ada7-1db86b751b3b'	System	19 Oct 2020 02:20:06
User entered 'None (0)'	System	19 Oct 2020 02:20:06

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:57', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ccad414-b9f0-4722-ada7-1db86b751b3b'	System	19 Oct 2020 02:20:06
User entered 'None (0)'	System	19 Oct 2020 02:20:06

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:19:59', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ccad414-b9f0-4722-ada7-1db86b751b3b'	System	19 Oct 2020 02:20:06
User entered 'No (N)'	System	19 Oct 2020 02:20:06

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-18T21:20:01', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ccad414-b9f0-4722-ada7-1db86b751b3b'	System	19 Oct 2020 02:20:06
User entered '18 Oct 2020 21:20'	System	19 Oct 2020 02:20:06

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 19:39:38



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 6'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:26:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec70d8b6-d980-4ae1-9f46-da607162d584'	System	20 Oct 2020 02:27:20
User entered 'None (0)'	System	20 Oct 2020 02:27:20

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:26:55', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec70d8b6-d980-4ae1-9f46-da607162d584'	System	20 Oct 2020 02:27:20
User entered 'None (0)'	System	20 Oct 2020 02:27:20

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:26:57', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec70d8b6-d980-4ae1-9f46-da607162d584'	System	20 Oct 2020 02:27:20
User entered 'None (0)'	System	20 Oct 2020 02:27:20

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:26:59', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec70d8b6-d980-4ae1-9f46-da607162d584'	System	20 Oct 2020 02:27:20
User entered 'None (0)'	System	20 Oct 2020 02:27:20

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:27:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec70d8b6-d980-4ae1-9f46-da607162d584'	System	20 Oct 2020 02:27:20
User entered 'None (0)'	System	20 Oct 2020 02:27:20

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:27:02', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec70d8b6-d980-4ae1-9f46-da607162d584'	System	20 Oct 2020 02:27:20
User entered 'None (0)'	System	20 Oct 2020 02:27:20



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:27:07', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec70d8b6-d980-4ae1-9f46-da607162d584'	System	20 Oct 2020 02:27:20
User entered 'No (N)'	System	20 Oct 2020 02:27:20

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-19T21:27:15', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec70d8b6-d980-4ae1-9f46-da607162d584'	System	20 Oct 2020 02:27:20
User entered '19 Oct 2020 21:27'	System	20 Oct 2020 02:27:20

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
Data entry locked.	System	14 Oct 2020 19:39:38
User entered 'Day 7'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:29', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'aba982f2-b19e-428f-b6c8-f905ea4215e9'	System	21 Oct 2020 03:55:47
User entered 'None (0)'	System	21 Oct 2020 03:55:47

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:31', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'aba982f2-b19e-428f-b6c8-f905ea4215e9'	System	21 Oct 2020 03:55:47
User entered 'None (0)'	System	21 Oct 2020 03:55:47

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:32', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'aba982f2-b19e-428f-b6c8-f905ea4215e9'	System	21 Oct 2020 03:55:47
User entered 'None (0)'	System	21 Oct 2020 03:55:47



US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:34', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'aba982f2-b19e-428f-b6c8-f905ea4215e9'	System	21 Oct 2020 03:55:47
User entered 'None (0)'	System	21 Oct 2020 03:55:47

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:35', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'aba982f2-b19e-428f-b6c8-f905ea4215e9'	System	21 Oct 2020 03:55:47
User entered 'None (0)'	System	21 Oct 2020 03:55:47

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:36', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'aba982f2-b19e-428f-b6c8-f905ea4215e9'	System	21 Oct 2020 03:55:47
User entered 'None (0)'	System	21 Oct 2020 03:55:47

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:40', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'aba982f2-b19e-428f-b6c8-f905ea4215e9'	System	21 Oct 2020 03:55:47
User entered 'No (N)'	System	21 Oct 2020 03:55:47

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-10-20T22:55:42', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'aba982f2-b19e-428f-b6c8-f905ea4215e9'	System	21 Oct 2020 03:55:47
User entered '20 Oct 2020 22:55'	System	21 Oct 2020 03:55:47

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 19:39:38

US3252665

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:18
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 19:39:38

**US3252665**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:04**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Oct 2020 03:48:12
	(b) (4)	



US3252665

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '21 Oct 2020'	Nancy Torrence (b) (4)	22 Oct 2020 03:48:12
	(b) (4)	

US3252665

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	22 Oct 2020 03:48:12
	(b) (4)	

US3252665

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	22 Oct 2020 03:48:12
	(b) (4)	

US3252665

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	22 Oct 2020 03:48:18
	(b) (4)	

US3252665

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'I'	System	22 Oct 2020 03:48:18

US3252665

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Oct 2020 01:57:52
	(b) (4)	

US3252665

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '28 Oct 2020'	Nancy Torrence (b) (4)	29 Oct 2020 01:57:52
	(b) (4)	

US3252665

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	29 Oct 2020 01:57:52
	(b) (4)	



US3252665

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	29 Oct 2020 01:57:52
	(b) (4)	

US3252665

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Oct 2020 01:57:58
	(b) (4)	

US3252665

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'I'	System	29 Oct 2020 01:57:58

US3252665

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Nov 2020 02:47:17
	(b) (4)	

US3252665

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '4 Nov 2020'	Nancy Torrence (b) (4)	05 Nov 2020 02:47:17
	(b) (4)	

US3252665

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	05 Nov 2020 02:47:17
	(b) (4)	

US3252665

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	05 Nov 2020 02:47:17
	(b) (4)	

US3252665

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Nov 2020 02:47:22
	(b) (4)	



US3252665

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'I'	System	05 Nov 2020 02:47:22

US3252665

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 17:00:15

US3252665

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '11 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 17:00:15

US3252665

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 17:00:15

US3252665

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'VISIT2'	System	11 Nov 2020 17:00:15

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '11 Nov 2020'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	



US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '10:22'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '11 Nov 2020 10:22'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '98.1' F	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '73'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'bpm'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '16'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	



US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'breaths/min'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '130'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '84'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '11 Nov 2020'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	



US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '11:28'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '11 Nov 2020 11:28'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '97.8' F	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '71'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'bpm'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '16'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	



US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'breaths/min'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '133'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '92'	Nancy Torrence (b) (4)	12 Nov 2020 04:13:52
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	12 Nov 2020 04:13:52

US3252665

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	12 Nov 2020 04:14:17
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	12 Nov 2020 04:14:17
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Nov 2020 04:15:09
	(b) (4)	



US3252665

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '11 Nov 2020'	Nancy Torrence (b) (4)	12 Nov 2020 04:15:09
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Urine (URINE)'	Nancy Torrence (b) (4)	12 Nov 2020 04:15:09
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Negative (NEGATIVE)'	Nancy Torrence (b) (4)	12 Nov 2020 04:15:09
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	12 Nov 2020 04:15:09
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	12 Nov 2020 04:15:09
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	12 Nov 2020 04:15:09
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:15:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered empty.	System	12 Nov 2020 04:15:09

US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	11 Nov 2020 17:00:31
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Joanna Gurrola Mahoney	11 Nov 2020 17:00:31
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 17:00:31

US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'MRNA-1273 OR PLACEBO'	System	11 Nov 2020 17:00:31

US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '11 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	11 Nov 2020 17:00:31

US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '10:58'	Joanna Gurrola Mahoney	11 Nov 2020 17:00:31
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '11 Nov 2020 10:58'	System	11 Nov 2020 17:00:31

US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney	11 Nov 2020 17:00:31
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'ONCE'	System	11 Nov 2020 17:00:31



US3252665

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'INTRAMUSCULAR'	System	11 Nov 2020 17:00:31

US3252665

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Nov 2020 04:16:44
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '11 Nov 2020'	Nancy Torrence (b) (4)	12 Nov 2020 04:16:44
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '10:50'	Nancy Torrence (b) (4)	12 Nov 2020 04:16:44
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '11 Nov 2020 10:50'	System	12 Nov 2020 04:16:44

US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:15:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '11 Nov 2020'	Nancy Torrence (b) (4)	12 Nov 2020 04:17:24
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:15:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 04:17:24

US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:15:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	12 Nov 2020 04:17:24
	(b) (4)	



US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:15:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '10:42'	Nancy Torrence (b) (4)	12 Nov 2020 04:17:24
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:15:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '11 Nov 2020 10:42'	System	12 Nov 2020 04:17:24

US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:15:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 04:17:24

US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:15:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Nancy Torrence (b) (4)	12 Nov 2020 04:17:24
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:15:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Nancy Torrence (b) (4)	12 Nov 2020 04:17:24
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:15:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered empty.	System	12 Nov 2020 04:17:24

US3252665

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	11 Nov 2020 17:00:37
	(b) (4)	

US3252665

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '1'	System	11 Nov 2020 17:00:37



US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:28:48', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ecd9ea8-9cfe-443a-8326-72bbf99dd757'	System	11 Nov 2020 17:29:10
User entered 'Yes (Y)'	System	11 Nov 2020 17:29:10

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:28:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ecd9ea8-9cfe-443a-8326-72bbf99dd757'	System	11 Nov 2020 17:29:10
User entered '97.8'	System	11 Nov 2020 17:29:10

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:28:56', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ecd9ea8-9cfe-443a-8326-72bbf99dd757'	System	11 Nov 2020 17:29:10
User entered 'No (N)'	System	11 Nov 2020 17:29:10

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:29:06', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3ecd9ea8-9cfe-443a-8326-72bbf99dd757'	System	11 Nov 2020 17:29:10
User entered '11 Nov 2020 11:29'	System	11 Nov 2020 17:29:10

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '11 Nov 2020 11:18'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '11 Nov 2020 13:48'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 17:00:31



US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:17:01', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f9c40c1-32c2-4440-a67a-f47f3da9161d'	System	12 Nov 2020 03:17:16
User entered 'Yes (Y)'	System	12 Nov 2020 03:17:16

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:17:04', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f9c40c1-32c2-4440-a67a-f47f3da9161d'	System	12 Nov 2020 03:17:16
User entered '97.4'	System	12 Nov 2020 03:17:16

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:17:07', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f9c40c1-32c2-4440-a67a-f47f3da9161d'	System	12 Nov 2020 03:17:16
User entered 'No (N)'	System	12 Nov 2020 03:17:16

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:17:11', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f9c40c1-32c2-4440-a67a-f47f3da9161d'	System	12 Nov 2020 03:17:16
User entered '11 Nov 2020 21:17'	System	12 Nov 2020 03:17:16

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '11 Nov 2020 14:43'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 2'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:15:10', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9f91ed62-1ca3-456e-871a-782d9b749419'	System	13 Nov 2020 02:15:34
User entered 'Yes (Y)'	System	13 Nov 2020 02:15:34



US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:15:13', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9f91ed62-1ca3-456e-871a-782d9b749419'	System	13 Nov 2020 02:15:34
User entered '97.8'	System	13 Nov 2020 02:15:34

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:15:16', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9f91ed62-1ca3-456e-871a-782d9b749419'	System	13 Nov 2020 02:15:34
User entered 'Yes (Y)'	System	13 Nov 2020 02:15:34

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DATA UPDATED ' (Site from System).	(b) (4), (b) (6)	14 Dec 2020 16:20:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 16:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:15:25', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9f91ed62-1ca3-456e-871a-782d9b749419'	System	13 Nov 2020 02:15:34
User entered '1'	System	13 Nov 2020 02:15:34

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:15:25', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9f91ed62-1ca3-456e-871a-782d9b749419' User entered '0'	System	13 Nov 2020 02:15:34
	System	13 Nov 2020 02:15:34

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:15:30', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9f91ed62-1ca3-456e-871a-782d9b749419'	System	13 Nov 2020 02:15:34
User entered '12 Nov 2020 20:15'	System	13 Nov 2020 02:15:34

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 3'	System	11 Nov 2020 17:00:31



US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:53', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e2705706-4df2-4e78-9f9c-b4334c960b79'	System	14 Nov 2020 04:51:11
User entered 'Yes (Y)'	System	14 Nov 2020 04:51:11

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:56', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e2705706-4df2-4e78-9f9c-b4334c960b79'	System	14 Nov 2020 04:51:11
User entered '97.3'	System	14 Nov 2020 04:51:11

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:51:01', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e2705706-4df2-4e78-9f9c-b4334c960b79'	System	14 Nov 2020 04:51:11
User entered 'Yes (Y)'	System	14 Nov 2020 04:51:11

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DATA UPDATED ' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 13:07:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	18 Nov 2020 16:04:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:51:06', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e2705706-4df2-4e78-9f9c-b4334c960b79'	System	14 Nov 2020 04:51:11
User entered '1'	System	14 Nov 2020 04:51:11

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:51:06', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e2705706-4df2-4e78-9f9c-b4334c960b79'	System	14 Nov 2020 04:51:11
User entered '0'	System	14 Nov 2020 04:51:11

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:51:09', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e2705706-4df2-4e78-9f9c-b4334c960b79'	System	14 Nov 2020 04:51:11
User entered '13 Nov 2020 22:51'	System	14 Nov 2020 04:51:11

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 17:00:31



US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 4'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:14', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'de8ad237-13fd-4bc7-8856-ef9667d5a77a'	System	15 Nov 2020 02:52:26
User entered 'Yes (Y)'	System	15 Nov 2020 02:52:26

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:17', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'de8ad237-13fd-4bc7-8856-ef9667d5a77a'	System	15 Nov 2020 02:52:26
User entered '97.6'	System	15 Nov 2020 02:52:26

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:31', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'de8ad237-13fd-4bc7-8856-ef9667d5a77a'	System	15 Nov 2020 02:52:26
User entered 'No (N)'	System	15 Nov 2020 02:52:26

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:34', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'de8ad237-13fd-4bc7-8856-ef9667d5a77a'	System	15 Nov 2020 02:52:26
User entered '14 Nov 2020 20:35'	System	15 Nov 2020 02:52:26

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 5'	System	11 Nov 2020 17:00:31



US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:46:55', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '6501109e-9fde-4c8b-a767-284bc01d82d7'	System	16 Nov 2020 04:47:05
User entered 'Yes (Y)'	System	16 Nov 2020 04:47:05

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:46:59', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '6501109e-9fde-4c8b-a767-284bc01d82d7'	System	16 Nov 2020 04:47:05
User entered '97.8'	System	16 Nov 2020 04:47:05

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:01', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '6501109e-9fde-4c8b-a767-284bc01d82d7'	System	16 Nov 2020 04:47:05
User entered 'No (N)'	System	16 Nov 2020 04:47:05

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:03', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '6501109e-9fde-4c8b-a767-284bc01d82d7'	System	16 Nov 2020 04:47:05
User entered '15 Nov 2020 22:47'	System	16 Nov 2020 04:47:05

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 6'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:10:58', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bdb0b763-23c2-4067-ad16-400667e5ff1d'	System	17 Nov 2020 05:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 05:11:10



US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:01', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bdb0b763-23c2-4067-ad16-400667e5ff1d' User entered '97.2'	System	17 Nov 2020 05:11:10
	System	17 Nov 2020 05:11:10

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:03', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bdb0b763-23c2-4067-ad16-400667e5ff1d'	System	17 Nov 2020 05:11:10
User entered 'No (N)'	System	17 Nov 2020 05:11:10

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:05', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'bdb0b763-23c2-4067-ad16-400667e5ff1d'	System	17 Nov 2020 05:11:10
User entered '16 Nov 2020 23:11'	System	17 Nov 2020 05:11:10

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 7'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:34', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e0562a20-e63e-413f-852c-f0f76cf85eed'	System	18 Nov 2020 04:14:46
User entered 'Yes (Y)'	System	18 Nov 2020 04:14:46

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:37', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e0562a20-e63e-413f-852c-f0f76cf85eed'	System	18 Nov 2020 04:14:46
User entered '96.9'	System	18 Nov 2020 04:14:46



US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:39', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e0562a20-e63e-413f-852c-f0f76cf85eed'	System	18 Nov 2020 04:14:46
User entered 'No (N)'	System	18 Nov 2020 04:14:46

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:41', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e0562a20-e63e-413f-852c-f0f76cf85eed'	System	18 Nov 2020 04:14:46
User entered '17 Nov 2020 22:14'	System	18 Nov 2020 04:14:46

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:29:13', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '512795a1-80b3-4be7-8d6c-807f2d264e29'	System	11 Nov 2020 17:29:36
User entered 'None (1)'	System	11 Nov 2020 17:29:36

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:29:19', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '512795a1-80b3-4be7-8d6c-807f2d264e29'	System	11 Nov 2020 17:29:36
User entered 'No (N)'	System	11 Nov 2020 17:29:36

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:29:22', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '512795a1-80b3-4be7-8d6c-807f2d264e29'	System	11 Nov 2020 17:29:36
User entered 'No (N)'	System	11 Nov 2020 17:29:36



US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:29:31', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '512795a1-80b3-4be7-8d6c-807f2d264e29'	System	11 Nov 2020 17:29:36
User entered 'None (1)'	System	11 Nov 2020 17:29:36

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:29:34', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '512795a1-80b3-4be7-8d6c-807f2d264e29'	System	11 Nov 2020 17:29:36
User entered '11 Nov 2020 11:29'	System	11 Nov 2020 17:29:36

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '11 Nov 2020 11:18'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '11 Nov 2020 13:48'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:17:22', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '7045fd7f-930c-4939-bbbd-d8de5c3038e9'	System	12 Nov 2020 03:21:06
User entered 'Does not interfere with activity (2)'	System	12 Nov 2020 03:21:06

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:17:41', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '7045fd7f-930c-4939-bbbd-d8de5c3038e9'	System	12 Nov 2020 03:21:06
User entered 'No (N)'	System	12 Nov 2020 03:21:06

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:17:47', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '7045fd7f-930c-4939-bbbd-d8de5c3038e9'	System	12 Nov 2020 03:21:06
User entered 'Yes (Y)'	System	12 Nov 2020 03:21:06



US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:20:57', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '7045fd7f-930c-4939-bbbd-d8de5c3038e9'	System	12 Nov 2020 03:21:06
User entered '30'	System	12 Nov 2020 03:21:06

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:01', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '7045fd7f-930c-4939-bbbd-d8de5c3038e9'	System	12 Nov 2020 03:21:06
User entered 'None (1)'	System	12 Nov 2020 03:21:06

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:03', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '7045fd7f-930c-4939-bbbd-d8de5c3038e9'	System	12 Nov 2020 03:21:06
User entered '11 Nov 2020 21:21'	System	12 Nov 2020 03:21:06

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '11 Nov 2020 14:43'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 2'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:15:40', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '01add63a-95eb-4158-9eaa-ec1c9e36cd05'	System	13 Nov 2020 02:18:40
User entered 'Does not interfere with activity (2)'	System	13 Nov 2020 02:18:40

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:17:36', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '01add63a-95eb-4158-9eaa-ec1c9e36cd05'	System	13 Nov 2020 02:18:40
User entered 'Yes (Y)'	System	13 Nov 2020 02:18:40



US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:18:02', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '01add63a-95eb-4158-9eaa-ec1c9e36cd05'	System	13 Nov 2020 02:18:40
User entered '55'	System	13 Nov 2020 02:18:40

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:18:05', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '01add63a-95eb-4158-9eaa-ec1c9e36cd05'	System	13 Nov 2020 02:18:40
User entered 'Yes (Y)'	System	13 Nov 2020 02:18:40

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:18:09', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '01add63a-95eb-4158-9eaa-ec1c9e36cd05'	System	13 Nov 2020 02:18:40
User entered '55'	System	13 Nov 2020 02:18:40

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:18:37', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '01add63a-95eb-4158-9eaa-ec1c9e36cd05'	System	13 Nov 2020 02:18:40
User entered 'None (1)'	System	13 Nov 2020 02:18:40

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:18:39', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '01add63a-95eb-4158-9eaa-ec1c9e36cd05'	System	13 Nov 2020 02:18:40
User entered '12 Nov 2020 20:18'	System	13 Nov 2020 02:18:40

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 3'	System	11 Nov 2020 17:00:31



US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:51:14', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a62cd5e0-81f3-4a0f-8a8c-bfeff064c12e'	System	14 Nov 2020 04:53:18
User entered 'Does not interfere with activity (2)'	System	14 Nov 2020 04:53:18

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:51:22', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a62cd5e0-81f3-4a0f-8a8c-bfeff064c12e'	System	14 Nov 2020 04:53:18
User entered 'Yes (Y)'	System	14 Nov 2020 04:53:18

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:52:27', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a62cd5e0-81f3-4a0f-8a8c-bfeff064c12e'	System	14 Nov 2020 04:53:18
User entered '70'	System	14 Nov 2020 04:53:18

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:52:30', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a62cd5e0-81f3-4a0f-8a8c-bfeff064c12e'	System	14 Nov 2020 04:53:18
User entered 'Yes (Y)'	System	14 Nov 2020 04:53:18

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:52:33', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a62cd5e0-81f3-4a0f-8a8c-bfeff064c12e'	System	14 Nov 2020 04:53:18
User entered '70'	System	14 Nov 2020 04:53:18

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:53:13', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a62cd5e0-81f3-4a0f-8a8c-bfeff064c12e'	System	14 Nov 2020 04:53:18
User entered 'None (1)'	System	14 Nov 2020 04:53:18

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:53:16', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a62cd5e0-81f3-4a0f-8a8c-bfeff064c12e'	System	14 Nov 2020 04:53:18
User entered '13 Nov 2020 22:53'	System	14 Nov 2020 04:53:18

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 17:00:31



US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 4'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:36:05', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a44c90ca-8162-439f-8a1d-031bb1d82dfa'	System	15 Nov 2020 02:53:28
User entered 'Does not interfere with activity (2)'	System	15 Nov 2020 02:53:28

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:36:21', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a44c90ca-8162-439f-8a1d-031bb1d82dfa'	System	15 Nov 2020 02:53:28
User entered 'No (N)'	System	15 Nov 2020 02:53:28

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:36:23', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a44c90ca-8162-439f-8a1d-031bb1d82dfa'	System	15 Nov 2020 02:53:28
User entered 'Yes (Y)'	System	15 Nov 2020 02:53:28

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:36:30', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a44c90ca-8162-439f-8a1d-031bb1d82dfa'	System	15 Nov 2020 02:53:28
User entered '30'	System	15 Nov 2020 02:53:28

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:36:32', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a44c90ca-8162-439f-8a1d-031bb1d82dfa'	System	15 Nov 2020 02:53:28
User entered 'None (1)'	System	15 Nov 2020 02:53:28

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:36:35', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'a44c90ca-8162-439f-8a1d-031bb1d82dfa'	System	15 Nov 2020 02:53:28
User entered '14 Nov 2020 20:36'	System	15 Nov 2020 02:53:28



US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 5'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:34', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '92d3f7d3-bad4-4dd1-95f7-2d8c543333be'	System	16 Nov 2020 04:48:10
User entered 'Does not interfere with activity (2)'	System	16 Nov 2020 04:48:10

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:40', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '92d3f7d3-bad4-4dd1-95f7-2d8c543333be'	System	16 Nov 2020 04:48:10
User entered 'No (N)'	System	16 Nov 2020 04:48:10

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:47', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '92d3f7d3-bad4-4dd1-95f7-2d8c543333be'	System	16 Nov 2020 04:48:10
User entered 'Yes (Y)'	System	16 Nov 2020 04:48:10

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:57', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '92d3f7d3-bad4-4dd1-95f7-2d8c543333be'	System	16 Nov 2020 04:48:10
User entered '20'	System	16 Nov 2020 04:48:10

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:48:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '92d3f7d3-bad4-4dd1-95f7-2d8c543333be'	System	16 Nov 2020 04:48:10
User entered 'None (1)'	System	16 Nov 2020 04:48:10



US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:48:08', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '92d3f7d3-bad4-4dd1-95f7-2d8c543333be'	System	16 Nov 2020 04:48:10
User entered '15 Nov 2020 22:48'	System	16 Nov 2020 04:48:10

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 6'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:50', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9626e225-5f38-4ae5-9e96-01de1dd1c0f8'	System	17 Nov 2020 05:12:12
User entered 'None (1)'	System	17 Nov 2020 05:12:12

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9626e225-5f38-4ae5-9e96-01de1dd1c0f8'	System	17 Nov 2020 05:12:12
User entered 'No (N)'	System	17 Nov 2020 05:12:12

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:56', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9626e225-5f38-4ae5-9e96-01de1dd1c0f8'	System	17 Nov 2020 05:12:12
User entered 'Yes (Y)'	System	17 Nov 2020 05:12:12

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:12:02', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9626e225-5f38-4ae5-9e96-01de1dd1c0f8'	System	17 Nov 2020 05:12:12
User entered '10'	System	17 Nov 2020 05:12:12



US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:12:05', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9626e225-5f38-4ae5-9e96-01de1dd1c0f8'	System	17 Nov 2020 05:12:12
User entered 'None (1)'	System	17 Nov 2020 05:12:12

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:12:07', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9626e225-5f38-4ae5-9e96-01de1dd1c0f8'	System	17 Nov 2020 05:12:12
User entered '16 Nov 2020 23:12'	System	17 Nov 2020 05:12:12

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 7'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:15:19', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3c5d83ad-a76e-4afc-81c1-23db9e12ca16'	System	18 Nov 2020 04:15:39
User entered 'None (1)'	System	18 Nov 2020 04:15:39

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:15:21', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3c5d83ad-a76e-4afc-81c1-23db9e12ca16'	System	18 Nov 2020 04:15:39
User entered 'No (N)'	System	18 Nov 2020 04:15:39

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:15:23', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3c5d83ad-a76e-4afc-81c1-23db9e12ca16'	System	18 Nov 2020 04:15:39
User entered 'Yes (Y)'	System	18 Nov 2020 04:15:39



US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:15:30', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3c5d83ad-a76e-4afc-81c1-23db9e12ca16'	System	18 Nov 2020 04:15:39
User entered '10'	System	18 Nov 2020 04:15:39

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:15:33', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3c5d83ad-a76e-4afc-81c1-23db9e12ca16'	System	18 Nov 2020 04:15:39
User entered 'None (1)'	System	18 Nov 2020 04:15:39

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:15:34', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '3c5d83ad-a76e-4afc-81c1-23db9e12ca16'	System	18 Nov 2020 04:15:39
User entered '17 Nov 2020 22:15'	System	18 Nov 2020 04:15:39

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:29:41', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8b99df45-550b-4f62-af68-60e8e5941a93'	System	11 Nov 2020 17:30:26
User entered 'None (0)'	System	11 Nov 2020 17:30:26

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:29:51', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8b99df45-550b-4f62-af68-60e8e5941a93'	System	11 Nov 2020 17:30:26
User entered 'None (0)'	System	11 Nov 2020 17:30:26



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:29:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8b99df45-550b-4f62-af68-60e8e5941a93'	System	11 Nov 2020 17:30:26
User entered 'None (0)'	System	11 Nov 2020 17:30:26

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:30:02', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8b99df45-550b-4f62-af68-60e8e5941a93'	System	11 Nov 2020 17:30:26
User entered 'None (0)'	System	11 Nov 2020 17:30:26

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:30:04', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8b99df45-550b-4f62-af68-60e8e5941a93'	System	11 Nov 2020 17:30:26
User entered 'None (0)'	System	11 Nov 2020 17:30:26

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:30:05', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8b99df45-550b-4f62-af68-60e8e5941a93'	System	11 Nov 2020 17:30:26
User entered 'None (0)'	System	11 Nov 2020 17:30:26

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:30:16', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8b99df45-550b-4f62-af68-60e8e5941a93'	System	11 Nov 2020 17:30:26
User entered 'No (N)'	System	11 Nov 2020 17:30:26

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T11:30:20', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '8b99df45-550b-4f62-af68-60e8e5941a93'	System	11 Nov 2020 17:30:26
User entered '11 Nov 2020 11:30'	System	11 Nov 2020 17:30:26

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '11 Nov 2020 11:18'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '11 Nov 2020 13:48'	System	11 Nov 2020 17:00:31



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 1, after vaccination (at home)'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:07', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f9bccff9-47d3-414a-afd7-728c86908bb9'	System	12 Nov 2020 03:21:28
User entered 'None (0)'	System	12 Nov 2020 03:21:28

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:10', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f9bccff9-47d3-414a-afd7-728c86908bb9'	System	12 Nov 2020 03:21:28
User entered 'None (0)'	System	12 Nov 2020 03:21:28

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:12', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f9bccff9-47d3-414a-afd7-728c86908bb9'	System	12 Nov 2020 03:21:28
User entered 'None (0)'	System	12 Nov 2020 03:21:28

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:14', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f9bccff9-47d3-414a-afd7-728c86908bb9'	System	12 Nov 2020 03:21:28
User entered 'None (0)'	System	12 Nov 2020 03:21:28

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:15', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f9bccff9-47d3-414a-afd7-728c86908bb9'	System	12 Nov 2020 03:21:28
User entered 'None (0)'	System	12 Nov 2020 03:21:28

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:16', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f9bccff9-47d3-414a-afd7-728c86908bb9'	System	12 Nov 2020 03:21:28
User entered 'None (0)'	System	12 Nov 2020 03:21:28

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:18', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f9bccff9-47d3-414a-afd7-728c86908bb9'	System	12 Nov 2020 03:21:28
User entered 'No (N)'	System	12 Nov 2020 03:21:28



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-11T21:21:20', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f9bccff9-47d3-414a-afd7-728c86908bb9'	System	12 Nov 2020 03:21:28
User entered '11 Nov 2020 21:21'	System	12 Nov 2020 03:21:28

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '11 Nov 2020 14:43'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '12 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 2'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:18:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ac7b9088-564a-4ce2-af90-aa857344f9d2'	System	13 Nov 2020 02:20:11
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Nov 2020 02:20:11

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:18:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ac7b9088-564a-4ce2-af90-aa857344f9d2'	System	13 Nov 2020 02:20:11
User entered 'Some interference with activity (2)'	System	13 Nov 2020 02:20:11

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:19:03', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ac7b9088-564a-4ce2-af90-aa857344f9d2'	System	13 Nov 2020 02:20:11
User entered 'No interference with activity (1)'	System	13 Nov 2020 02:20:11

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:19:06', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ac7b9088-564a-4ce2-af90-aa857344f9d2'	System	13 Nov 2020 02:20:11
User entered 'None (0)'	System	13 Nov 2020 02:20:11



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:19:58', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ac7b9088-564a-4ce2-af90-aa857344f9d2'	System	13 Nov 2020 02:20:11
User entered 'None (0)'	System	13 Nov 2020 02:20:11

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:20:04', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ac7b9088-564a-4ce2-af90-aa857344f9d2'	System	13 Nov 2020 02:20:11
User entered 'Some interference with activity not requiring medical attention (2)'	System	13 Nov 2020 02:20:11

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:20:07', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ac7b9088-564a-4ce2-af90-aa857344f9d2'	System	13 Nov 2020 02:20:11
User entered 'No (N)'	System	13 Nov 2020 02:20:11

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-12T20:20:09', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ac7b9088-564a-4ce2-af90-aa857344f9d2'	System	13 Nov 2020 02:20:11
User entered '12 Nov 2020 20:20'	System	13 Nov 2020 02:20:11

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '12 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '13 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 3'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:19', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e8c653bc-a00d-4a51-9a14-cc65bce205ad'	System	14 Nov 2020 04:50:43
User entered 'No interference with activity (1)'	System	14 Nov 2020 04:50:43



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:24', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e8c653bc-a00d-4a51-9a14-cc65bce205ad'	System	14 Nov 2020 04:50:43
User entered 'None (0)'	System	14 Nov 2020 04:50:43

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:26', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e8c653bc-a00d-4a51-9a14-cc65bce205ad'	System	14 Nov 2020 04:50:43
User entered 'None (0)'	System	14 Nov 2020 04:50:43

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:28', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e8c653bc-a00d-4a51-9a14-cc65bce205ad'	System	14 Nov 2020 04:50:43
User entered 'None (0)'	System	14 Nov 2020 04:50:43

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:29', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e8c653bc-a00d-4a51-9a14-cc65bce205ad'	System	14 Nov 2020 04:50:43
User entered 'None (0)'	System	14 Nov 2020 04:50:43

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:32', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e8c653bc-a00d-4a51-9a14-cc65bce205ad'	System	14 Nov 2020 04:50:43
User entered 'None (0)'	System	14 Nov 2020 04:50:43

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:37', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e8c653bc-a00d-4a51-9a14-cc65bce205ad'	System	14 Nov 2020 04:50:43
User entered 'No (N)'	System	14 Nov 2020 04:50:43

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-13T22:50:42', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'e8c653bc-a00d-4a51-9a14-cc65bce205ad'	System	14 Nov 2020 04:50:43
User entered '13 Nov 2020 22:50'	System	14 Nov 2020 04:50:43

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '13 Nov 2020 12:00'	System	11 Nov 2020 17:00:31



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '14 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 4'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:47', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '161ac43f-d81b-423b-b631-f932e4d315e8'	System	15 Nov 2020 02:52:57
User entered 'No interference with activity (1)'	System	15 Nov 2020 02:52:57

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '161ac43f-d81b-423b-b631-f932e4d315e8'	System	15 Nov 2020 02:52:57
User entered 'None (0)'	System	15 Nov 2020 02:52:57

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:51', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '161ac43f-d81b-423b-b631-f932e4d315e8'	System	15 Nov 2020 02:52:57
User entered 'None (0)'	System	15 Nov 2020 02:52:57

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:52', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '161ac43f-d81b-423b-b631-f932e4d315e8'	System	15 Nov 2020 02:52:57
User entered 'None (0)'	System	15 Nov 2020 02:52:57

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:54', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '161ac43f-d81b-423b-b631-f932e4d315e8'	System	15 Nov 2020 02:52:57
User entered 'None (0)'	System	15 Nov 2020 02:52:57

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:55', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '161ac43f-d81b-423b-b631-f932e4d315e8'	System	15 Nov 2020 02:52:57
User entered 'None (0)'	System	15 Nov 2020 02:52:57



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:35:58', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '161ac43f-d81b-423b-b631-f932e4d315e8'	System	15 Nov 2020 02:52:57
User entered 'No (N)'	System	15 Nov 2020 02:52:57

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-14T20:36:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '161ac43f-d81b-423b-b631-f932e4d315e8'	System	15 Nov 2020 02:52:57
User entered '14 Nov 2020 20:36'	System	15 Nov 2020 02:52:57

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '14 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '15 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 5'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:08', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2acbbffa-a638-4d2e-b99f-88297cc1204a'	System	16 Nov 2020 04:47:30
User entered 'No interference with activity (1)'	System	16 Nov 2020 04:47:30

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:14', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2acbbffa-a638-4d2e-b99f-88297cc1204a'	System	16 Nov 2020 04:47:30
User entered 'No interference with activity (1)'	System	16 Nov 2020 04:47:30

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:16', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2acbbffa-a638-4d2e-b99f-88297cc1204a'	System	16 Nov 2020 04:47:30
User entered 'None (0)'	System	16 Nov 2020 04:47:30



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:19', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2acbbffa-a638-4d2e-b99f-88297cc1204a'	System	16 Nov 2020 04:47:30
User entered 'None (0)'	System	16 Nov 2020 04:47:30

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:21', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2acbbffa-a638-4d2e-b99f-88297cc1204a'	System	16 Nov 2020 04:47:30
User entered 'None (0)'	System	16 Nov 2020 04:47:30

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:22', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2acbbffa-a638-4d2e-b99f-88297cc1204a'	System	16 Nov 2020 04:47:30
User entered 'None (0)'	System	16 Nov 2020 04:47:30

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:24', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2acbbffa-a638-4d2e-b99f-88297cc1204a'	System	16 Nov 2020 04:47:30
User entered 'No (N)'	System	16 Nov 2020 04:47:30

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-15T22:47:27', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2acbbffa-a638-4d2e-b99f-88297cc1204a'	System	16 Nov 2020 04:47:30
User entered '15 Nov 2020 22:47'	System	16 Nov 2020 04:47:30

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '15 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

**US3252665**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:15:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '16 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 6'	System	11 Nov 2020 17:00:31



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:09', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2c6d3fb-1785-4514-9135-ecb26ba2213d'	System	17 Nov 2020 05:11:45
User entered 'None (0)'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:17', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2c6d3fb-1785-4514-9135-ecb26ba2213d'	System	17 Nov 2020 05:11:45
User entered 'Some interference with activity (2)'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:22', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2c6d3fb-1785-4514-9135-ecb26ba2213d'	System	17 Nov 2020 05:11:45
User entered 'None (0)'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:24', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2c6d3fb-1785-4514-9135-ecb26ba2213d'	System	17 Nov 2020 05:11:45
User entered 'None (0)'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:25', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2c6d3fb-1785-4514-9135-ecb26ba2213d'	System	17 Nov 2020 05:11:45
User entered 'None (0)'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:28', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2c6d3fb-1785-4514-9135-ecb26ba2213d'	System	17 Nov 2020 05:11:45
User entered 'None (0)'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:31', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2c6d3fb-1785-4514-9135-ecb26ba2213d'	System	17 Nov 2020 05:11:45
User entered 'No (N)'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-16T23:11:34', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2c6d3fb-1785-4514-9135-ecb26ba2213d'	System	17 Nov 2020 05:11:45
User entered '16 Nov 2020 23:11'	System	17 Nov 2020 05:11:45



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '16 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '17 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	11 Nov 2020 17:00:31
User entered 'Day 7'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:45', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f2df3bd-da8f-4d79-94dc-d041b370123c'	System	18 Nov 2020 04:15:08
User entered 'None (0)'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f2df3bd-da8f-4d79-94dc-d041b370123c'	System	18 Nov 2020 04:15:08
User entered 'No interference with activity (1)'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:51', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f2df3bd-da8f-4d79-94dc-d041b370123c'	System	18 Nov 2020 04:15:08
User entered 'None (0)'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:52', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f2df3bd-da8f-4d79-94dc-d041b370123c'	System	18 Nov 2020 04:15:08
User entered 'None (0)'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:53', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f2df3bd-da8f-4d79-94dc-d041b370123c'	System	18 Nov 2020 04:15:08
User entered 'None (0)'	System	18 Nov 2020 04:15:08



US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:55', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f2df3bd-da8f-4d79-94dc-d041b370123c'	System	18 Nov 2020 04:15:08
User entered 'None (0)'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:14:57', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f2df3bd-da8f-4d79-94dc-d041b370123c'	System	18 Nov 2020 04:15:08
User entered 'No (N)'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-17T22:15:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1f2df3bd-da8f-4d79-94dc-d041b370123c'	System	18 Nov 2020 04:15:08
User entered '17 Nov 2020 22:15'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '17 Nov 2020 12:00'	System	11 Nov 2020 17:00:31

**US3252665**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:15:04**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '18 Nov 2020 11:59'	System	11 Nov 2020 17:00:31

US3252665

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	17 Nov 2020 05:12:12
User entered 'Day 8'	System	17 Nov 2020 05:12:12

US3252665

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 11 Aug 2021 22:15:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-18T22:53:21', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1e08183f-b0c9-4a51-9390-50f12cce4b37'	System	19 Nov 2020 04:53:26
User entered 'No (N)'	System	19 Nov 2020 04:53:26

US3252665

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-18T22:53:23', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1e08183f-b0c9-4a51-9390-50f12cce4b37'	System	19 Nov 2020 04:53:26
User entered '18 Nov 2020 22:53'	System	19 Nov 2020 04:53:26



US3252665

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 05:12:12

US3252665

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 05:12:12

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	17 Nov 2020 05:11:45
User entered 'Day 8'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:15:04

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-18T22:53:29', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '08561d1d-25be-431a-ab08-e79d5985a0a7'	System	19 Nov 2020 04:53:35
User entered 'No interference with activity (1)'	System	19 Nov 2020 04:53:35

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-18T22:53:31', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '08561d1d-25be-431a-ab08-e79d5985a0a7'	System	19 Nov 2020 04:53:35
User entered '18 Nov 2020 22:53'	System	19 Nov 2020 04:53:35

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	18 Nov 2020 04:15:08
User entered 'Day 9'	System	18 Nov 2020 04:15:08



US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:15:04

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-19T13:42:33', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'd659a5b5-53d3-4642-8280-270376c3a070'	System	19 Nov 2020 19:42:41
User entered 'None (0)'	System	19 Nov 2020 19:42:41

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:15:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-19T13:42:35', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'd659a5b5-53d3-4642-8280-270376c3a070'	System	19 Nov 2020 19:42:41
User entered '19 Nov 2020 13:42'	System	19 Nov 2020 19:42:41

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	17 Nov 2020 05:11:45
User entered 'Day 8'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-18T22:53:34', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b0afe765-23a9-444f-a22a-b56c3ec372ab'	System	19 Nov 2020 04:53:40
User entered 'No (N)'	System	19 Nov 2020 04:53:40

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-18T22:53:36', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b0afe765-23a9-444f-a22a-b56c3ec372ab'	System	19 Nov 2020 04:53:40
User entered '18 Nov 2020 22:53'	System	19 Nov 2020 04:53:40

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '18 Nov 2020 12:00'	System	17 Nov 2020 05:11:45



US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '19 Nov 2020 11:59'	System	17 Nov 2020 05:11:45

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:15:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
Data entry locked.	System	18 Nov 2020 04:15:08
User entered 'Day 9'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:15:04

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 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-19T13:42:38', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'cef2420a-9bcc-4ab3-ad2a-5bca09ecf537'	System	19 Nov 2020 19:42:45
User entered 'No (N)'	System	19 Nov 2020 19:42:45

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:15:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-11-19T13:42:40', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'cef2420a-9bcc-4ab3-ad2a-5bca09ecf537'	System	19 Nov 2020 19:42:45
User entered '19 Nov 2020 13:42'	System	19 Nov 2020 19:42:45

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:15:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 04:15:08

US3252665

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:15:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:27:23
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 04:15:08

US3252665

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	19 Nov 2020 03:28:25
	(b) (4)	

US3252665

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '18 Nov 2020'	Shannon Moyer (b) (4)	19 Nov 2020 03:28:25
	(b) (4)	



US3252665

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	19 Nov 2020 03:28:25
	(b) (4)	

US3252665

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Shannon Moyer (b) (4)	19 Nov 2020 03:28:25
	(b) (4)	

US3252665

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	19 Nov 2020 03:28:32
	(b) (4)	

US3252665

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'I'	System	19 Nov 2020 03:28:32

US3252665

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Nov 2020 02:55:05
	(b) (4)	

US3252665

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '25 Nov 2020'	Shannon Moyer (b) (4)	26 Nov 2020 02:55:05
	(b) (4)	

US3252665

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	26 Nov 2020 02:55:05
	(b) (4)	

US3252665

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Shannon Moyer (b) (4)	26 Nov 2020 02:55:05
	(b) (4)	



US3252665

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Nov 2020 02:55:10
	(b) (4)	

US3252665

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'I'	System	26 Nov 2020 02:55:10

US3252665

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	03 Dec 2020 03:02:25
	(b) (4)	

US3252665

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '2 Dec 2020'	Shannon Moyer (b) (4)	03 Dec 2020 03:02:25
	(b) (4)	

US3252665

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	03 Dec 2020 03:02:25
	(b) (4)	

US3252665

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Shannon Moyer (b) (4)	03 Dec 2020 03:02:25
	(b) (4)	

US3252665

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	03 Dec 2020 03:02:30
	(b) (4)	

US3252665

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'I'	System	03 Dec 2020 03:02:30



US3252665

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	10 Dec 2020 03:50:16
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '9 Dec 2020'	Shannon Moyer (b) (4)	10 Dec 2020 03:50:16
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	10 Dec 2020 03:50:16
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'VISIT3'	System	10 Dec 2020 03:50:16

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '9 Dec 2020'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '09:12'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '9 Dec 2020 09:12'	System	10 Dec 2020 03:52:13



US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '98.6' F	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '67'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'bpm'	System	10 Dec 2020 03:52:13

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '16'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'breaths/min'	System	10 Dec 2020 03:52:13

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '128'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	



US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	10 Dec 2020 03:52:13

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '85'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:13
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'mmHg'	System	10 Dec 2020 03:52:13

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22

US3252665

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22

US3252665

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'No (N)'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:22
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:04

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered empty.	Shannon Moyer (b) (4)	10 Dec 2020 03:52:22
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:37
	(b) (4)	



US3252665

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '9 Dec 2020'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:37
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered '09:35'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:37
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered '9 Dec 2020 09:35'	System	10 Dec 2020 03:52:37

US3252665

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 04:12:05
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	10 Dec 2020 03:52:42
	(b) (4)	

US3252665

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'I'	System	10 Dec 2020 03:52:42

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2020-12-26T21:26:18', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'fb76bfe8-f0e5-497b-9086-3f773b59bccc'	System	27 Dec 2020 03:27:18
User entered 'No (N)'	System	27 Dec 2020 03:27:18

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2020-12-26T21:26:24', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'fb76bfe8-f0e5-497b-9086-3f773b59bccc'	System	27 Dec 2020 03:27:18
User entered 'Yes (Y)'	System	27 Dec 2020 03:27:18

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-12-26T21:26:49', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'fb76bfe8-f0e5-497b-9086-3f773b59bcc'	System	27 Dec 2020 03:27:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 03:27:18

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2020-12-26T21:27:07', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'fb76bfe8-f0e5-497b-9086-3f773b59bccc'	System	27 Dec 2020 03:27:18
User entered '26 Dec 2020 21:27:07'	System	27 Dec 2020 03:27:18



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-01-01T06:30:53', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ebc2bae1-358c-4775-99f5-ad54e6e7d733'	System	01 Jan 2021 12:31:06
User entered 'No (N)'	System	01 Jan 2021 12:31:06

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-01-01T06:30:56', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ebc2bae1-358c-4775-99f5-ad54e6e7d733'	System	01 Jan 2021 12:31:06
User entered 'No (N)'	System	01 Jan 2021 12:31:06

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-01-01T06:30:59', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ebc2bae1-358c-4775-99f5-ad54e6e7d733'	System	01 Jan 2021 12:31:06
User entered '01 Jan 2021 06:30:59'	System	01 Jan 2021 12:31:06

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:37:13

US3252665

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-01-08T06:32:29', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec2a6a34-b850-47b8-9f24-84e88e54aa1a'	System	08 Jan 2021 12:34:34
User entered 'No (N)'	System	08 Jan 2021 12:34:34

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-01-08T06:34:27', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec2a6a34-b850-47b8-9f24-84e88e54aa1a'	System	08 Jan 2021 12:34:34
User entered 'No (N)'	System	08 Jan 2021 12:34:34

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-01-08T06:34:29', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ec2a6a34-b850-47b8-9f24-84e88e54aa1a'	System	08 Jan 2021 12:34:34
User entered '08 Jan 2021 06:34:29'	System	08 Jan 2021 12:34:34

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-01-15T14:06:53', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c147603a-c830-41b7-ab67-0ae9d79879e0'	System	15 Jan 2021 20:07:03
User entered 'No (N)'	System	15 Jan 2021 20:07:03



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-01-15T14:06:57', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c147603a-c830-41b7-ab67-0ae9d79879e0'	System	15 Jan 2021 20:07:03
User entered 'No (N)'	System	15 Jan 2021 20:07:03

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-01-15T14:06:59', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c147603a-c830-41b7-ab67-0ae9d79879e0'	System	15 Jan 2021 20:07:03
User entered '15 Jan 2021 14:06:59'	System	15 Jan 2021 20:07:03

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-01-24T20:46:01', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '4a2e8190-b3d8-4d94-9cd5-e1aa0334887c'	System	25 Jan 2021 02:46:31
User entered 'No (N)'	System	25 Jan 2021 02:46:31

US3252665

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-01-24T20:46:05', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '4a2e8190-b3d8-4d94-9cd5-e1aa0334887c'	System	25 Jan 2021 02:46:31
User entered 'No (N)'	System	25 Jan 2021 02:46:31

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-01-24T20:46:29', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '4a2e8190-b3d8-4d94-9cd5-e1aa0334887c'	System	25 Jan 2021 02:46:31
User entered '24 Jan 2021 20:46:29'	System	25 Jan 2021 02:46:31



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-02-02T21:19:15', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2667f98-02eb-4a12-aedb-3421201c7a8c'	System	03 Feb 2021 03:19:25
User entered 'No (N)'	System	03 Feb 2021 03:19:25

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-02-02T21:19:18', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2667f98-02eb-4a12-aedb-3421201c7a8c'	System	03 Feb 2021 03:19:25
User entered 'No (N)'	System	03 Feb 2021 03:19:25

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-02-02T21:19:21', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f2667f98-02eb-4a12-aedb-3421201c7a8c'	System	03 Feb 2021 03:19:25
User entered '02 Feb 2021 21:19:21'	System	03 Feb 2021 03:19:25

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-02-05T07:36:37', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1df88501-48c7-4c6a-8767-2c51b928316b'	System	05 Feb 2021 13:36:44
User entered 'No (N)'	System	05 Feb 2021 13:36:44

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-02-05T07:36:39', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1df88501-48c7-4c6a-8767-2c51b928316b'	System	05 Feb 2021 13:36:44
User entered 'No (N)'	System	05 Feb 2021 13:36:44

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-02-05T07:36:42', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '1df88501-48c7-4c6a-8767-2c51b928316b'	System	05 Feb 2021 13:36:44
User entered '05 Feb 2021 07:36:42'	System	05 Feb 2021 13:36:44

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-02-14T12:18:10', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b56565c6-558c-48fc-9ddc-bd8ca9d129d2'	System	14 Feb 2021 18:18:21
User entered 'No (N)'	System	14 Feb 2021 18:18:21



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-02-14T12:18:12', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b56565c6-558c-48fc-9ddc-bd8ca9d129d2'	System	14 Feb 2021 18:18:21
User entered 'No (N)'	System	14 Feb 2021 18:18:21

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-02-14T12:18:15', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'b56565c6-558c-48fc-9ddc-bd8ca9d129d2'	System	14 Feb 2021 18:18:21
User entered '14 Feb 2021 12:18:15'	System	14 Feb 2021 18:18:21

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-02-19T05:14:10', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f0e49203-acf8-4d85-a181-135e6c6bcf16'	System	19 Feb 2021 11:14:16
User entered 'No (N)'	System	19 Feb 2021 11:14:16

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-02-19T05:14:12', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f0e49203-acf8-4d85-a181-135e6c6bcf16'	System	19 Feb 2021 11:14:16
User entered 'No (N)'	System	19 Feb 2021 11:14:16

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-02-19T05:14:14', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'f0e49203-acf8-4d85-a181-135e6c6bcf16'	System	19 Feb 2021 11:14:16
User entered '19 Feb 2021 05:14:14'	System	19 Feb 2021 11:14:16



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-03-02T08:17:22-06:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '5e16419d-cc53-43dc-98ac-baec09c35797'	System	02 Mar 2021 14:17:29
User entered 'No (N)'	System	02 Mar 2021 14:17:29

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-03-02T08:17:25-06:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '5e16419d-cc53-43dc-98ac-baec09c35797'	System	02 Mar 2021 14:17:29
User entered 'No (N)'	System	02 Mar 2021 14:17:29

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-03-02T08:17:27-06:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '5e16419d-cc53-43dc-98ac-baec09c35797'	System	02 Mar 2021 14:17:29
User entered '02 Mar 2021 08:17:27'	System	02 Mar 2021 14:17:29

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-03-06T07:12:34-06:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'cf5c4ccf-5a60-4ba1-933a-d0a809886392'	System	06 Mar 2021 13:12:41
User entered 'No (N)'	System	06 Mar 2021 13:12:41

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-03-06T07:12:36-06:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'cf5c4ccf-5a60-4ba1-933a-d0a809886392'	System	06 Mar 2021 13:12:41
User entered 'No (N)'	System	06 Mar 2021 13:12:41

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-03-06T07:12:38-06:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'cf5c4ccf-5a60-4ba1-933a-d0a809886392'	System	06 Mar 2021 13:12:41
User entered '06 Mar 2021 07:12:38'	System	06 Mar 2021 13:12:41

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-03-15T13:45:29-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9e1db1b7-ec1d-4bf3-a7ad-c94e4438026d' User entered 'No (N)'	System	15 Mar 2021 18:46:18
	System	15 Mar 2021 18:46:18



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-03-15T13:46:11-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9e1db1b7-ec1d-4bf3-a7ad-c94e4438026d' User entered 'No (N)'	System	15 Mar 2021 18:46:18

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-03-15T13:46:13-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '9e1db1b7-ec1d-4bf3-a7ad-c94e4438026d' User entered '15 Mar 2021 13:46:13'	System	15 Mar 2021 18:46:18
	System	15 Mar 2021 18:46:18

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-03-23T11:39:33-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '57c52183-93d8-4c71-a4e7-3cb89b2e9376'	System	23 Mar 2021 16:39:44
User entered 'No (N)'	System	23 Mar 2021 16:39:44

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-03-23T11:39:36-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '57c52183-93d8-4c71-a4e7-3cb89b2e9376'	System	23 Mar 2021 16:39:44
User entered 'No (N)'	System	23 Mar 2021 16:39:44

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-03-23T11:39:38-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '57c52183-93d8-4c71-a4e7-3cb89b2e9376'	System	23 Mar 2021 16:39:44
User entered '23 Mar 2021 11:39:38'	System	23 Mar 2021 16:39:44



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-03-28T12:10:59-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '78e9f2d9-192b-44ec-a8dd-e9eec052202b' User entered 'No (N)'	System	28 Mar 2021 17:11:24
	System	28 Mar 2021 17:11:24

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-03-28T12:11:01-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '78e9f2d9-192b-44ec-a8dd-e9eec052202b'	System	28 Mar 2021 17:11:24
User entered 'No (N)'	System	28 Mar 2021 17:11:24

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-03-28T12:11:03-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '78e9f2d9-192b-44ec-a8dd-e9eec052202b' User entered '28 Mar 2021 12:11:03'	System	28 Mar 2021 17:11:24
	System	28 Mar 2021 17:11:24

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-04-13T15:48:42-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2c07afc2-ea13-4193-9d5e-c6010299f415' User entered 'Yes (Y)'	System	18 Apr 2021 17:06:53
	System	18 Apr 2021 17:06:53

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-04-13T15:48:47-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2c07afc2-ea13-4193-9d5e-c6010299f415'	System	18 Apr 2021 17:06:53
User entered 'No (N)'	System	18 Apr 2021 17:06:53

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-04-13T15:48:51-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2c07afc2-ea13-4193-9d5e-c6010299f415'	System	18 Apr 2021 17:06:53
User entered 'No (N)'	System	18 Apr 2021 17:06:53

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-04-13T17:44:30-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2c07afc2-ea13-4193-9d5e-c6010299f415'	System	18 Apr 2021 17:06:53
User entered 'No (N)'	System	18 Apr 2021 17:06:53



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-04-13T17:44:49-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '2c07afc2-ea13-4193-9d5e-c6010299f415'	System	18 Apr 2021 17:06:53
User entered '13 Apr 2021 17:44:49'	System	18 Apr 2021 17:06:53

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-04-18T12:06:18-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '35726108-0ad0-43e1-96bb-bfd7c60fdf8d' User entered 'No (N)'	System	18 Apr 2021 17:07:02
	System	18 Apr 2021 17:07:02

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-04-18T12:06:20-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '35726108-0ad0-43e1-96bb-bfd7c60fdf8d' User entered 'No (N)'	System	18 Apr 2021 17:07:02
	System	18 Apr 2021 17:07:02

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-04-18T12:06:27-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '35726108-0ad0-43e1-96bb-bfd7c60fdf8d' User entered '18 Apr 2021 12:06:27'	System	18 Apr 2021 17:07:02
	System	18 Apr 2021 17:07:02

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-04-23T08:20:23-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c07838aa-27e9-433c-b720-8b92a01854dd' User entered 'No (N)'	System	23 Apr 2021 13:20:35
	System	23 Apr 2021 13:20:35

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-04-23T08:20:26-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c07838aa-27e9-433c-b720-8b92a01854dd'	System	23 Apr 2021 13:20:35
User entered 'No (N)'	System	23 Apr 2021 13:20:35

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-04-23T08:20:29-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'c07838aa-27e9-433c-b720-8b92a01854dd'	System	23 Apr 2021 13:20:35
User entered '23 Apr 2021 08:20:29'	System	23 Apr 2021 13:20:35

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[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 (482c3d30ea1b85a0)', Time: '2021-04-30T07:22:38-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '4e97c27d-b19a-4957-b42b-b15e027926cf' User entered 'No (N)'	System	30 Apr 2021 12:22:56

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

Have you been exposed to someone with 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 (482c3d30ea1b85a0)', Time: '2021-04-30T07:22:46-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '4e97c27d-b19a-4957-b42b-b15e027926cf'	System	30 Apr 2021 12:22:56
User entered 'No (N)'	System	30 Apr 2021 12:22:56

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-04-30T07:22:48-05:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: '4e97c27d-b19a-4957-b42b-b15e027926cf' User entered '30 Apr 2021 07:22:48'	System	30 Apr 2021 12:22:56
	System	30 Apr 2021 12:22:56

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:37:13



**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:37:13

**US3252665**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 12:37:13



**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 12:37:13

**US3252665**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:37:13
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 12:37:13

US3252665

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:15:04**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:50:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-03-02T08:17:41-06:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ae03f358-79f5-46e1-abd3-e6f5049ec3ed'	System	02 Mar 2021 14:17:49
User entered 'No (N)'	System	02 Mar 2021 14:17:49

US3252665

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:15:04

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:50:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (482c3d30ea1b85a0)', Time: '2021-03-02T08:17:44-06:00', User OID: 'PatientReportedOutcome (US3252665)', ODM File OID: 'ae03f358-79f5-46e1-abd3-e6f5049ec3ed'	System	02 Mar 2021 14:17:49
User entered '02 Mar 2021 08:17:44'	System	02 Mar 2021 14:17:49

US3252665

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 07:48:51

US3252665

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered '8 Jan 2021'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 07:48:51



US3252665

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 07:48:51

US3252665

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 07:48:51

US3252665

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 07:49:00

US3252665

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:10:22
User entered 'I'	System	05 Feb 2021 07:49:00

US3252665

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 09:39:33
User entered 'Yes (Y)' reason for change: Data Entry Error		04 Mar 2021 09:36:55
User entered 'No (N)'		04 Mar 2021 04:02:17

US3252665

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	04 Mar 2021 09:39:33
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	04 Mar 2021 09:39:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 09:39:33
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	04 Mar 2021 09:36:55
User entered '3 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 09:36:55
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:02:17

US3252665

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 09:39:33
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error		04 Mar 2021 09:36:55
User entered empty.		04 Mar 2021 04:02:17

US3252665

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 09:39:33
User entered 'Patient was not contacted and visit was not completed.' reason for change: Data Entry Error		04 Mar 2021 09:36:55
User entered empty.		04 Mar 2021 04:02:17



US3252665

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 04:02:20

US3252665

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User entered 'I'	System	04 Mar 2021 04:02:20

US3252665

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 16:07:06

US3252665

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:07:06

US3252665

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:07:06

US3252665

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 16:07:06

US3252665

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 16:07:15

US3252665

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:04:07
User entered 'I'	System	31 Mar 2021 16:07:15



US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:11
	(b) (4)	

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:11
	(b) (4)	

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:11
	(b) (4)	

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 04:35:11

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:04

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:27
	(b) (4)	

**US3252665**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:15:04**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:49:03

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:04

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:27
	(b) (4)	

**US3252665**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:15:04**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
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 09:49:03



US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:04

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:27
	(b) (4)	

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:04

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'mRNA-1273 (mRNA-1273)'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:27
	(b) (4)	

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:04

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 05:14:30
User entered 'mRNA-1273 (mRNA-1273)'	Shannon Moyer (b) (4) (b) (4)	08 Jan 2021 04:35:27

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:04

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 05:14:30
User entered 'mRNA-1273 (mRNA-1273)'	Shannon Moyer (b) (4) (b) (4)	08 Jan 2021 04:35:27

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:04

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'No (N)'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:27
	(b) (4)	

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:04

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered empty.	System	08 Jan 2021 04:35:27

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:04

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered empty.	System	08 Jan 2021 04:35:27

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:39
	(b) (4)	



US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:39
	(b) (4)	

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered '11:42'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:39
	(b) (4)	

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered '7 Jan 2021 11:42'	System	08 Jan 2021 04:35:39

US3252665

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:15:04**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:50
	(b) (4)	

US3252665

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:15:04

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered '7 Jan 2021'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:50
	(b) (4)	

US3252665

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:15:04**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered '11:41'	Shannon Moyer (b) (4)	08 Jan 2021 04:35:50
	(b) (4)	

**US3252665**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:15:04**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:03:11
User entered '7 Jan 2021 11:41'	System	08 Jan 2021 04:35:50

US3252665

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:15:04

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 05:57:00
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'As per Sub-I, if a solicited local or systemic AR continues beyond 7 days after dosing, the participant will be prompted daily to capture solicited AR in the eDiary until resolution. Adverse reactions recorded in diaries beyond Day 7 will be reviewed by the investigator. As per protocol this is already documented on the eDiary and does not need to be reported as an AE.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:55:55
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 08:32:05
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	15 Oct 2020 04:09:29



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:15:04**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:17:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:07:49
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	15 Oct 2020 04:07:59

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:15:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:02:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:02:30
Data point term sent to Coder	System	28 Oct 2020 20:08:59
User entered 'Metformin'	(b) (4), (b) (6)	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 20:08:40

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'Polycystic Ovarian Syndrome'	(b) (4), (b) (6)	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '500'	(b) (4), (b) (6)	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:08:40

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'three times daily (TID)'	(b) (4), (b) (6)	28 Oct 2020 20:08:40



US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:08:40

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:08:40

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '22 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 20:08:40

**US3252665**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:08:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:08:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:08:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:08:40
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:08:40



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 20:08:40

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:15:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 20:08:40

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:15:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:02:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:02:31
Data point term sent to Coder	System	28 Oct 2020 20:10:00
User entered 'Tylenol'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:15:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:15:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:30:39
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'eDiary dose 1 log lines 1 and 2.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	16 Dec 2020 16:28:00
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:17:30
User entered 'Headache'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '500'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Oct 2020 20:09:39



US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:15:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:15:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:15:04

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '14 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:15:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 20:09:39



US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '14 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	29 Oct 2020 04:49:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 20:09:39

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User entered empty.	System	28 Oct 2020 20:09:39

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User entered empty.	System	28 Oct 2020 20:09:39

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:15:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:59
User entered empty.	System	28 Oct 2020 20:09:39

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:15:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 16:07:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 16:07:07
Data point term sent to Coder	System	18 Nov 2020 16:06:36
User entered 'TYLENOL'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:15:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

US3252665

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:15:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of headache did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:31:05
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of headache did not meet the AE reporting criteria.' answered with ' the solicited adverse reaction of headache did not meet the AE reporting criteria. ' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	16 Dec 2020 16:28:12
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the headache is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of headache did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:17:51

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '500'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:15:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 16:06:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:15:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'twice daily (BID)'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 16:06:12

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 16:06:12



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:15:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User closed query 'Per DM CLR: Please review START DATE of this medication as this is before the occurrence of HEADACHE which started 12 NOV 2020 per Diary. Either update CM START DATE or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 10:36:53
Query 'Per DM CLR: Please review START DATE of this medication as this is before the occurrence of HEADACHE which started 12 NOV 2020 per Diary. Either update CM START DATE or confirm in query response that CM was given during this recorded date.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:17:53
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 07:17:47
User opened query 'Per DM CLR: Please review START DATE of this medication as this is before the occurrence of HEADACHE which started 12 NOV 2020 per Diary. Either update CM START DATE or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:20:21
User entered '11 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered '12 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:08:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 16:06:12

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User entered '2'	System	18 Nov 2020 16:06:12

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User entered '1'	System	18 Nov 2020 16:06:12

US3252665

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:15:04**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:25:00
User entered '804 (804)'	System	18 Nov 2020 16:06:12



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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:15:04**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:20:03
User entered 'No (N)'	Nancy Torrence (b) (4)	15 Oct 2020 04:08:22
	(b) (4)	