

US3342085 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:06:47

All time stamps listed in this document are displayed in GMT

US3342085

Form: Participant Creation

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

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Participant ID

US3342085

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

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US3342085

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

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

US3342085

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3342085

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

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

US3342085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3342085

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

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Were any significant conditions reported?

Yes ☒  
No ☐

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US3342085

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 15:03:52

Generated On: 09 Jun 2021 17:06:47

Condition	ATTENTION DEFICIT DISORDER
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3342085

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 15:03:52

Generated On: 09 Jun 2021 17:06:47

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342085

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 15:03:52

Generated On: 09 Jun 2021 17:06:47

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342085

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 15:03:52

Generated On: 09 Jun 2021 17:06:47

Condition	FACIAL BOTOX
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342085

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 15:03:52

Generated On: 09 Jun 2021 17:06:47

Condition	FACIAL DYSPORT
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342085

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 15:03:52

Generated On: 09 Jun 2021 17:06:47

Condition	FACIAL JUVEDERM
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3342085

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	17 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:48 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 13:48
Height ( <i>xxx.x</i> )	167.5 cm
Weight ( <i>xxx.x</i> )	76.9 kg
BMI ( <i>xxx.x</i> )	27.40922 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)	

US3342085

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3342085

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Date of assessment (dd MMM yyyy) 17 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

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

Date of last menstruation unknown False



US3342085

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 17 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3342085

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

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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**

PROPERTY MANAGER

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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

US3342085

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

<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>	

US3342085

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

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

US3342085

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Mar 2021 15:03:52

Generated On: 09 Jun 2021 17:06:47

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

What was the participant's randomization number? 105103

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 ☒

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Height	ND - Not Done
Weight	ND - Not Done

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	13:48 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 13:48
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	108 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:30
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	111 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG



US3342085

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

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.*

US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

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) \_\_\_\_\_

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

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

Treatment Date and Time (derived) 17 AUG 2020 14:59

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

US3342085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

14:34 (24 HR)

Collection date and time (derived)

17 AUG 2020 14:34

US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:36	17 AUG 2020 14:36
Nasopharyngeal Swab 2	No		

US3342085

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**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

98.9 °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 AUG 2020 15:29

PC Open Date & Time

17 AUG 2020 15:19

PC Close Date & Time

17 AUG 2020 17:49

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**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 97.5 °F

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

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

PC Time Stamp	17 AUG 2020 21:59
PC Open Date & Time	17 AUG 2020 18:44
PC Close Date & Time	18 AUG 2020 11:59



US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 12:42

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**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

97.9 °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

19 AUG 2020 20:54

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 13:12

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

21 AUG 2020 19:38

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

22 AUG 2020 22:28

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 22:56

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 15:32

PC Open Date & Time

17 AUG 2020 15:19

PC Close Date & Time

17 AUG 2020 17:49

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 21:53

PC Open Date & Time

17 AUG 2020 18:44

PC Close Date & Time

18 AUG 2020 11:59



US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:40

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 20:24

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**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

20 AUG 2020 13:11

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**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

21 AUG 2020 19:35

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**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

22 AUG 2020 22:28

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 22:56

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**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 ☐

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 15:32
PC Open Date & Time	17 AUG 2020 15:19
PC Close Date & Time	17 AUG 2020 17:49



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**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 ☐

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 21:54
PC Open Date & Time	17 AUG 2020 18:44
PC Close Date & Time	18 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**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 ☒

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 12:41
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

52 of 2362

EAB) (1725)

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:24
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**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

54 of 2362

EAB) (1725)

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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 ☒

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 19:35
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**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)

58 of 2362

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 22:28
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**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

60 of 2362

EAB) (1725)

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 22:55
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3342085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3342085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

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

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	15:28 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 15:28
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	118 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

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

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)	16 SEP 2020
Time of assessment (00:00-23:59)	16:38 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 16:38
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	109 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3342085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

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.*



US3342085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	16 SEP 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)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 16 SEP 2020

What was the treatment time? (00:00-23:59) 16:07 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 16:07

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

US3342085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 SEP 2020
Collection time (00:00-23:59)	15:49 (24 HR)
Collection date and time (derived)	16 SEP 2020 15:49

US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:52	16 SEP 2020 15:52
Nasopharyngeal Swab 2	No		

US3342085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 16:41

PC Open Date & Time

16 SEP 2020 16:27

PC Close Date & Time

16 SEP 2020 18:57

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.2 °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	17 SEP 2020 03:41
PC Open Date & Time	16 SEP 2020 19:52
PC Close Date & Time	17 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

17 SEP 2020 13:10

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59



US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

19 SEP 2020 00:18

---

PC Open Date & Time

18 SEP 2020 12:00

---

PC Close Date & Time

19 SEP 2020 11:59

---

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 18:43

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

20 SEP 2020 21:07

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °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

22 SEP 2020 07:22

---

PC Open Date & Time

21 SEP 2020 12:00

---

PC Close Date & Time

22 SEP 2020 11:59

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US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 23:42

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 16:42

PC Open Date & Time

16 SEP 2020 16:27

PC Close Date & Time

16 SEP 2020 18:57

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 03:42

PC Open Date & Time

16 SEP 2020 19:52

PC Close Date & Time

17 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 13:11

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59



US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 00:18

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**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

19 SEP 2020 18:43

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 21:07

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**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

22 SEP 2020 07:22

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 23:42

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**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 ☐

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 16:42
PC Open Date & Time	16 SEP 2020 16:27
PC Close Date & Time	16 SEP 2020 18:57

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**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 ☐



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 03:42
PC Open Date & Time	16 SEP 2020 19:52
PC Close Date & Time	17 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**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

97 of 2362

EAB) (1725)

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 13:12
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**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

99 of 2362

EAB) (1725)

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**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  
EAB) (1725)

101 of 2362

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 18:44
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

103 of 2362

EAB) (1725)



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 21:08
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**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)

105 of 2362

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**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 ☒

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 23:43
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3342085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3342085

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:33:56

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 14:35
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	106 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

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.*

US3342085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

14:58 (24 HR)

Collection date and time (derived)

16 OCT 2020 14:58

US3342085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:33:57

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 07:44:54

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 18:07:50

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 00:02:09
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 NOV 2020 16:09:14
Patient Cloud Open Date & Time	14 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
123 of 2362	

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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22 NOV 2020 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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29 NOV 2020 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 DEC 2020 09:07:43
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 <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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2020 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 15:04:27

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 12:25:31

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 JAN 2021 18:33:58

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 23:16:03

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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

14 JAN 2021 12:55:02

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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

22 JAN 2021 18:12:35

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 12:06:14
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 FEB 2021 20:01:28
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 19:45:56

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 FEB 2021 10:07:50

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 02:00:38
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 05:45:57
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 17:35:54

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 15:12:59

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 15:26:08

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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04 APR 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 17:46:06

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 10:49:21

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 18:00:57

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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06 JUN 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 <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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	18 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	22 AUG 2021 23:59
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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	01 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	15 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2021 23:59
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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	22 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2021 23:59
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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	29 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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="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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	06 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59
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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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17 OCT 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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°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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	01 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2021 23:59



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	15 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59
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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 FEB 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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27 MAR 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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10 APR 2022 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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="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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 <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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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12 JUN 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

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19 JUN 2022 23:59



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

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03 JUL 2022 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Open Date & Time](#)

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06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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24 JUL 2022 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

27 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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="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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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17 AUG 2022 00:01

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21 AUG 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	07 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 SEP 2022 23:59



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 SEP 2022 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**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 ☐

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	28 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 OCT 2022 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

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

US3342085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:06:47

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
<a href="#">Yes</a>	<a href="#">No</a>	<a href="#">02 MAR 2021 05:18:48</a>

US3342085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3342085

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

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

Visit date (dd MMM yyyy)	30 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	14:46 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 14:46
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

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.*



US3342085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

14:03 (24 HR)

Collection date and time (derived)

30 MAR 2021 14:03

US3342085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:32:33

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:32:33

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

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*

**US3342085**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:47**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Date of Contact	16 NOV 2020
Time of Contact	10:45
Date and Time of Contact (derived)	16 NOV 2020 10:45
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 NOV 2020
------	-------------

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

O2 Saturation	91 %
---------------	------

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

Temperature	98.7 F
-------------	--------

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

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

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

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

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EAB) (1725)

332 of 2362

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

336 of 2362

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

340 of 2362

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

344 of 2362

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

Date of Visit	16 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	16 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3342085

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 NOV 2020
Day 5	No	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3342085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	SICKD1

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 10:53
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3342085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3342085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 NOV 2020

US3342085

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

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

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

Visit date (dd MMM yyyy)	12 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3342085

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Date of updated informed consent ( <i>dd MMM yyyy</i> )	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3342085

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3342085

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 14:30
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3342085

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	16:09 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 16:09
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3342085

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

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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



US3342085

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

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	12 JAN 2021
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)	

US3342085

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

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 15:32 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 15:32

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

US3342085

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

15:25 (24 HR)

Collection date and time (derived)

12 JAN 2021 15:25

US3342085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00 - 23:59)	15:29
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Collection Date and Time (derived)	12 JAN 2021 15:29
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US3342085

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

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3342085

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

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)	23 FEB 2021
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 11:35
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

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)	23 FEB 2021
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 12:44
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3342085

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

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.*

US3342085

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	23 FEB 2021
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)	

US3342085

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 12:14 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 12:14

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

US3342085

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 MAR 2021

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

Comments ATTEMPTED 3 PHONE CALLS

*If Contact Not Made, please provide Comments*

US3342085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3342085

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	30 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	14:46 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 14:46
Temperature ( <i>xxx.x</i> )	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	88 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342085

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

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.*

US3342085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

14:03 (24 HR)

Collection date and time (derived)

30 MAR 2021 14:03

US3342085

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: 09 Jun 2021 17:06:47

Visit Date	23 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

US3342085

Folder: **Unscheduled 23 Feb 2021**

Form: **Immunogenicity Assessment**

Data signed: (b) (4) 12 Mar 2021 23:51:50

Generated On: **09 Jun 2021 17:06:47**

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

23 FEB 2021

Collection time (*00:00-23:59*)

12:06 (24 HR)

Collection date and time (derived)

23 FEB 2021 12:06

US3342085

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:32:52

Generated On: 09 Jun 2021 17:06:47

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

AEID

Adverse event

VIRAL UPPER RESPIRATORY  
INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

383 of 2362

EAB) (1725)



US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3342085

Folder: Adverse Events

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Generated On: 09 Jun 2021 17:06:47

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SUBJECT CALLED SITE AT 08:05  
(16NOV2020) AND REPORTED  
HAVING HA/ST/LOSS OF  
SMELL/COUGH STARTING  
13NOV2020. PT WENT TO PCP  
AND RECIEVED COVID RAPID  
TEST (RESULT (-)). GIVEN  
VIRTUSSIN 5ML PO PRN SINCE  
15NOV2020 BY PCP. RAPID TEST  
WAS ON 15NOV2020.

ALSO REPORTS CHILLS,  
FATIGUE, SOB, CONGESTION,  
RHINITIS, DIARRHEA.

---

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

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US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

AEID	USA-US203-2021-MRNA-1273-P30 1000007
Adverse event	APPENDICITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

386 of 2362

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

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SUBJECT REPORTED BEING  
ADMITTED TO THE HOSPITAL  
FOR ABDOMINAL PAIN ON  
02FEB2021 AND HAVING AN  
APPENDECTOMY FOR  
APPENDICITIS ON 03FEB2021.  
SUBJECT WAS DISCHARGED  
FROM THE HOSPITAL  
POST-SURGERY ON 03FEB2021.

PATIENT FILLED OUT MEDICAL  
RELEASE FORM 30MAR2021.  
PATIENT'S COVID-19 TEST  
FROM HOSPITAL WAS  
NEGATIVE. PATIENT ALSO  
REPORTED THAT THERE WAS  
NO UNDERLYING  
CONDITION/RISK FACTORS  
THAT CAUSED THE  
APPENDICITIS. PATIENT WAS  
UNSURE ABOUT LAB WORK  
DONE AT HOSPITAL. PATIENT  
DID HAVE CT SCAN ON  
02FEB2021 (REPORTED ON  
CONPROCEDURES), WHICH  
CONFIRMED APPENDICITIS  
DIAGNOSIS. AWAITING  
MEDICAL RECORDS FOR  
FURTHER INFORMATION.

---

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

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US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

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

Yes ☒

No ☐

---

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

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US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Name of Medication ADDERALL

Prophylaxis Yes ☐  
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

390 of 2362

EAB) (1725)

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Name of Medication CITALOPRAM HYDROBROMIDE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

392 of 2362

EAB) (1725)

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Name of Medication LEVOTHYROXINE SODIUM

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

394 of 2362

EAB) (1725)

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

396 of 2362

EAB) (1725)

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Name of Medication VIRTUSSIN

Prophylaxis Yes ☐  
No ☒

Indication VIRAL URI (AE)

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

398 of 2362

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 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)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Name of Medication KETORALAC

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS AE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

400 of 2362

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Name of Medication BOTOX

Prophylaxis Yes ☐  
No ☒

Indication ELECTIVE (COSMETIC)

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

402 of 2362

EAB) (1725)

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Name of Medication DYSPORT

Prophylaxis Yes ☐  
No ☒

Indication ELECTIVE (COSMETIC)

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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)

404 of 2362

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

Name of Medication JUVEDERM

Prophylaxis Yes ☐  
No ☒

Indication ELECTIVE (COSMETIC)

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

406 of 2362

EAB) (1725)

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Mar 2021 15:03:51

Generated On: 09 Jun 2021 17:06:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 23:51:49

Generated On: 09 Jun 2021 17:06:47

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
03 FEB 2021	APPENDECTOMY	Adverse Event	
02 FEB 2021	CT SCAN	Diagnostic	

US3342085

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:47

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

US3342085

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:47

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 ☐

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

SAEID	USA-US203-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

SAEID	USA-US203-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/FEB/2021 12:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

SAEID	USA-US203-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/MAR/2021 08:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

SAEID	USA-US203-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/MAR/2021 09:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 15:29:05

Generated On: 09 Jun 2021 17:06:47

SAEID	USA-US203-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	31/MAR/2021 10:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3342085 (Prod: Tekton Research- Austin)

**US3342085**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:06:47**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:48:26
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'US3342085'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:21:10

US3342085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:22

US3342085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:21:10

US3342085

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Clinic (Clinic)'	Andrew Bell (b) (4)	17 Aug 2020 19:29:22

**US3342085**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'SCRN'	System	17 Aug 2020 19:29:22

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:24:21



US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '51'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:34

**US3342085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:06:47**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'YEARS'	System	17 Aug 2020 19:29:34

**US3342085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:06:47**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '51'	System	17 Aug 2020 19:29:45

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Female (F)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'I'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:29:34



US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:47

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:29:34

US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '17 Aug 2020'	Andrew Bell (b) (4)	17 Aug 2020 19:29:45

US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'Aug 2020'	System	17 Aug 2020 19:29:45



US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '2020'	System	17 Aug 2020 19:29:45

US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Amendment 2 (2)'	Andrew Bell (b) (4)	17 Aug 2020 19:29:45

US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:45

US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:45

US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:29:45

US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4)	
	Andrew Bell (b) (4)	17 Aug 2020 19:29:45
	(b) (4)	

US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:21:10

US3342085

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'I'	System	17 Aug 2020 19:29:51



US3342085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:06:47

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Andrew Bell (b) (4)	17 Aug 2020 19:29:51

US3342085

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:06:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Andrew Bell (b) (4)	17 Aug 2020 19:34:08

US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User coded data point as SOC: Psychiatric disorders, HLT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:36:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:36:21
Data point term sent to Coder	System	17 Aug 2020 19:35:27
User entered 'Attention Deficit Disorder'	Andrew Bell (b) (4)	17 Aug 2020 19:34:33

US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'UN UNK 2011'	Andrew Bell (b) (4)	17 Aug 2020 19:34:33

US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:34:33

US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:34:33

US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Andrew Bell (b) (4)	17 Aug 2020 19:34:33

US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:34:33



US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'Jan 2011'	System	17 Aug 2020 19:34:33

US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '2011'	System	17 Aug 2020 19:34:33

US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	17 Aug 2020 19:34:33

US3342085

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	17 Aug 2020 19:34:33

US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:36:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:36:20
Data point term sent to Coder	System	17 Aug 2020 19:35:27
User entered 'Depression'	Andrew Bell (b) (4)	17 Aug 2020 19:34:49

US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'UN UNK 2005'	Andrew Bell (b) (4)	17 Aug 2020 19:34:49

US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:34:49

US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Andrew Bell (b) (4)	17 Aug 2020 19:34:49



US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Andrew Bell (b) (4)	17 Aug 2020 19:34:49

US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:34:49

US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'Jan 2005'	System	17 Aug 2020 19:34:49

US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '2005'	System	17 Aug 2020 19:34:49

US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	17 Aug 2020 19:34:49

US3342085

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	17 Aug 2020 19:34:49

US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:36:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 19:36:20
Data point term sent to Coder	System	17 Aug 2020 19:35:27
User entered 'Hypothyroidism'	Andrew Bell (b) (4)	17 Aug 2020 19:35:08

US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'UN UNK 2015'	Andrew Bell (b) (4)	17 Aug 2020 19:35:08



US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:35:08

US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:35:08

US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Andrew Bell (b) (4)	17 Aug 2020 19:35:08

US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:35:08

US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'Jan 2015'	System	17 Aug 2020 19:35:08

US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '2015'	System	17 Aug 2020 19:35:08

US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	17 Aug 2020 19:35:08

US3342085

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	17 Aug 2020 19:35:08



US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 21:22:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 21:22:42
Data point term sent to Coder	System	18 Mar 2021 21:22:32
User entered 'Facial Botox'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:03

US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'UN UNK 2014'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:03

US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered '0'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:03

US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:03

US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered empty.	Ethan Shotton (b) (4)	18 Mar 2021 21:22:03

US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered '0'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:03

US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'Jan 2014'	System	18 Mar 2021 21:22:03

US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '2014'	System	18 Mar 2021 21:22:03



US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	18 Mar 2021 21:22:03

US3342085

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:06:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	18 Mar 2021 21:22:03

US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 04:25:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 04:25:24
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	29 Mar 2021 15:03:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Skin cosmetic procedure, LLT: Skin cosmetic procedure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 13:08:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 13:08:51
Data point term sent to Coder	System	18 Mar 2021 21:22:33
User entered 'Facial Dysport'	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 21:22:21

US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'UN UNK 2015'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:21

US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered '0'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:21

US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:21

US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered empty.	Ethan Shotton (b) (4)	18 Mar 2021 21:22:21

US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered '0'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:21



US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'Jan 2015'	System	18 Mar 2021 21:22:21

US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '2015'	System	18 Mar 2021 21:22:21

US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	18 Mar 2021 21:22:21

US3342085

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:06:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	18 Mar 2021 21:22:21

US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 08:06:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 08:06:03
Data point term sent to Coder	System	18 Mar 2021 21:23:34
User entered 'Facial Juvederm'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:35

US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'Un UNK 2017'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:35

US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered '0'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:35

US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:35



US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered empty.	Ethan Shotton (b) (4)	18 Mar 2021 21:22:35

US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered '0'	Ethan Shotton (b) (4)	18 Mar 2021 21:22:35

US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'Jan 2017'	System	18 Mar 2021 21:22:35

US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '2017'	System	18 Mar 2021 21:22:35

US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	18 Mar 2021 21:22:35

US3342085

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:06:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	18 Mar 2021 21:22:35

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Andrew Bell (b) (4)	17 Aug 2020 19:31:06

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '17 Aug 2020'	Andrew Bell (b) (4)	17 Aug 2020 19:31:06



US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '13:48'	Andrew Bell (b) (4)	17 Aug 2020 19:31:06

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '17 Aug 2020 13:48'	System	17 Aug 2020 19:31:06

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '167.5' cm	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:31:06
DataPoint set to visible.	(b) (4) System	17 Aug 2020 19:29:51

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '76.9' kg	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:31:06
DataPoint set to visible.	(b) (4) System	17 Aug 2020 19:29:51

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
Amendment Manager: User entered '27.40922'	System	17 Sep 2020 00:00:42
User entered '27.4'	System	17 Aug 2020 19:31:06
DataPoint set to visible.	System	17 Aug 2020 19:29:51

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'kg/m2'	System	17 Aug 2020 19:31:06
DataPoint set to visible.	System	17 Aug 2020 19:29:51

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Please clarify why Temp, pulse, RR, and BP were not done.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:35:36
Query 'Please clarify why Temp, pulse, RR, and BP were not done.' answered with 'PER PROTOCOL, PULSE,RR, AND BP TO BE ENTERED AS "ND" WHEN SCREENING AND VISIT 1 DONE TOGETHER.' (Site from CRA).	Morgan Schulle (b) (4) (b) (4)	25 Sep 2020 18:54:21
User opened query 'Please clarify why Temp, pulse, RR, and BP were not done.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:13:50
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:46:42
User entered '98.8' F	Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:31:06

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty; reason for change Data Entry Error	(b) (4)	
	John Luna (b) (4)	25 Aug 2020 17:46:42
User entered 'Oral (Oral)'	Andrew Bell (b) (4)	17 Aug 2020 19:31:06
	(b) (4)	



US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:31:06

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:46:42
User entered '108'	Andrew Bell (b) (4)	17 Aug 2020 19:31:06
	(b) (4)	

**US3342085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'bpm'	System	17 Aug 2020 19:31:06

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:46:42
User entered '16'	Andrew Bell (b) (4)	17 Aug 2020 19:31:06
	(b) (4)	

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'breaths/min'	System	17 Aug 2020 19:31:06

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:46:42
User entered '125'	Andrew Bell (b) (4)	17 Aug 2020 19:31:06
	(b) (4)	

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'mmHg'	System	17 Aug 2020 19:31:06

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:46:42
User entered '81'	Andrew Bell (b) (4)	17 Aug 2020 19:31:06
	(b) (4)	



US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'mmHg'	System	17 Aug 2020 19:31:06

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03

US3342085

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03

US3342085

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Andrew Bell (b) (4)	17 Aug 2020 19:32:39

US3342085

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	
User entered '17 Aug 2020' reason for change: Data Entry Error	System	18 Sep 2020 16:30:05
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	Morgan Schulle (b) (4)	18 Sep 2020 16:30:05
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	18 Sep 2020 16:29:56
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 16:29:56
User entered '17 Aug 2020'	System	18 Sep 2020 16:29:56
	Morgan Schulle (b) (4)	
	(b) (4)	
	System	16 Sep 2020 21:13:43
	Andrew Bell (b) (4)	17 Aug 2020 19:32:39
	(b) (4)	

US3342085

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '17 Aug 2020'	Andrew Bell (b) (4)	17 Aug 2020 19:33:02

US3342085

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:47

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:02

US3342085

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:47

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:02



US3342085

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:47

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:02

US3342085

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Andrew Bell (b) (4)	17 Aug 2020 19:33:02

US3342085

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:47

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:33:02

US3342085

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Andrew Bell (b) (4)	17 Aug 2020 19:33:02

US3342085

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:47

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:33:02

US3342085

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:15

US3342085

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '17 Aug 2020'	Andrew Bell (b) (4)	17 Aug 2020 19:33:15

US3342085

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Urine (URINE)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:15



US3342085

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Negative (NEGATIVE)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:15

US3342085

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:15

US3342085

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:15

US3342085

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Andrew Bell (b) (4)	17 Aug 2020 19:33:15

**US3342085**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:06:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	17 Aug 2020 19:33:15

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53



US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53



US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Property manager'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'I'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53



US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:33:53

US3342085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:35:44

US3342085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '17 Aug 2020'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:35:44

US3342085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Clinic (Clinic)'	Andrew Bell (b) (4)	17 Aug 2020 19:35:44

US3342085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'VISIT1'	System	17 Aug 2020 19:35:44

US3342085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:44:36

US3342085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:07:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:07:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 19:44:36
User entered '105103' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:44:36



US3342085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:44:36

US3342085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:47

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)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:46:09

US3342085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:47

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)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	Andrew Bell (b) (4)	17 Aug 2020 19:46:09

US3342085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:47

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:09

US3342085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:47

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:09

US3342085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:09

US3342085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:47

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'No (N)'	Ethan Shotton (b) (4)	18 Mar 2021 20:57:43
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:11
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:43:26

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:47:01
User entered '167.5' cm	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10



US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:47:01
User entered '76.9' kg	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:47:01
User entered '167.5' cm	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:47:01
User entered '76.9' kg	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '17 Aug 2020'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '13:48'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '17 Aug 2020 13:48'	System	17 Aug 2020 21:09:10



US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '98.8' F	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Oral (Oral)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '108'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'bpm'	System	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'breaths/min'	System	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '125'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10



US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '81'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:47:01
User entered '167.5' cm	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Aug 2020 17:47:01
User entered '76.9' kg	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '17 Aug 2020'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10



US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:03:34
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol 30 minute assessment required.' (Site from System).	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:27
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 21:09:10
User entered '15:30'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '17 Aug 2020 15:30'	System	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '98.9' F	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Oral (Oral)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '111'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'bpm'	System	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '12'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10



US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'breaths/min'	System	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '115'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '72'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	17 Aug 2020 21:09:10

US3342085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	John Luna (b) (4)	25 Aug 2020 17:47:11
User entered 'Yes (Y)'	Andrew Bell (b) (4)	17 Aug 2020 19:59:30
	(b) (4)	

US3342085

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty; reason for change Data Entry Error	(b) (4)	
	John Luna (b) (4)	25 Aug 2020 17:47:11
User entered '17 Aug 2020'	Andrew Bell (b) (4)	17 Aug 2020 19:59:30
	(b) (4)	

US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:23:12
Query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' answered with 'pregnancy test listed for screening visit only' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 22:38:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 22:37:57
User opened query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:55:30
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:55:22



US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

Was the pregnancy test performed?

Audit	User	Time (GMT)
Query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Per CRF guidelines, both screening and baseline pregnancy test CRFs are to be completed if dosed same day as screening' (Site from DM).	Eileen Euperio (b) (4)	25 Sep 2020 14:42:13
User opened query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:09:01
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 19:57:48
Query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Understood. However, per the current eCRF Completion Guidelines, pages 15 and 16, under "DATA REQUIREMENTS", the information required to be input is listed as "Pregnancy Test (if applicable)" in the Screening Visit folder and again information is required to be input listed as "Pregnancy Test (if applicable)" in the Visit 1 Day 1 folder.' (Site from DM).	Darrell O'Brien (b) (4)	11 Sep 2020 23:11:02

PRODUCTION RELEASE (v12.003  
EAB) (1725)

624 of 2362

US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

Was the pregnancy test performed?

Audit	User	Time (GMT)
User opened query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 07:45:26
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 07:45:26
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'Per eCRF guide, data entered on both pages.' (Site from DM).	John Luna (b) (4)	09 Sep 2020 23:42:18
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 09:15:44
User entered 'Yes (Y)'	Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:35:55

US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:37:57
User entered '17 Aug 2020'	Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:35:55

US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:37:57
User entered 'Urine (URINE)'	Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:35:55

US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:37:57
User entered 'Negative (NEGATIVE)'	Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:35:55

US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	(b) (4)	17 Aug 2020 19:35:55
	Andrew Bell (b) (4)	
	(b) (4)	

US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:35:55

US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:35:55



US3342085

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered empty.	System	17 Aug 2020 19:35:55

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 20:01:54

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 20:01:54

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

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)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	Andrew Bell (b) (4)	17 Aug 2020 20:01:54

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 20:01:54

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '17 Aug 2020'	Andrew Bell (b) (4)	17 Aug 2020 20:01:54

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '14:59'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 20:01:54

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '17 Aug 2020 14:59'	System	17 Aug 2020 20:01:54



US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Left Arm (LEFT ARM)'	Andrew Bell (b) (4)	17 Aug 2020 20:01:54

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'ONCE'	System	17 Aug 2020 20:01:54

US3342085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 20:01:54

US3342085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:25

US3342085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '17 Aug 2020'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:25

US3342085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '14:34'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:25

US3342085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '17 Aug 2020 14:34'	System	17 Aug 2020 19:46:25

US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '17 Aug 2020'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:38



US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:46:38

US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:38

US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '14:36'	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:38

US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '17 Aug 2020 14:36'	System	17 Aug 2020 19:46:38

US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andrew Bell (b) (4) (b) (4)	17 Aug 2020 19:46:38

US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Aug 2020 21:09:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 21:09:39
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:39
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 19:46:38
User entered empty.	Andrew Bell (b) (4)	17 Aug 2020 19:46:38

US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Andrew Bell (b) (4)	17 Aug 2020 19:46:38

US3342085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:47

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered empty.	System	17 Aug 2020 19:46:38



US3342085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:09:44

US3342085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '1'	System	17 Aug 2020 21:09:44

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:28:53', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '5905c7a4-93d9-411e-9ddc-a07369303876' User entered 'Yes (Y)'	System	17 Aug 2020 20:29:14
	System	17 Aug 2020 20:29:14

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:28:59', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '5905c7a4-93d9-411e-9ddc-a07369303876' User entered '98.9'	System	17 Aug 2020 20:29:14
	System	17 Aug 2020 20:29:14

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:29:04', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '5905c7a4-93d9-411e-9ddc-a07369303876'	System	17 Aug 2020 20:29:14
User entered 'No (N)'	System	17 Aug 2020 20:29:14

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:29:09', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '5905c7a4-93d9-411e-9ddc-a07369303876'	System	17 Aug 2020 20:29:14
User entered '17 Aug 2020 15:29'	System	17 Aug 2020 20:29:14

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Aug 2020 15:19'	System	17 Aug 2020 20:01:54



US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Aug 2020 17:49'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:55:06', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '571484b1-dbea-46bd-ae03-5258f9ef31c8' User entered 'Yes (Y)'	System	18 Aug 2020 02:59:10
	System	18 Aug 2020 02:59:10

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:59:02', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '571484b1-dbea-46bd-ae03-5258f9ef31c8' User entered '97.5'	System	18 Aug 2020 02:59:10
	System	18 Aug 2020 02:59:10

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:59:05', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '571484b1-dbea-46bd-ae03-5258f9ef31c8'	System	18 Aug 2020 02:59:10
User entered 'No (N)'	System	18 Aug 2020 02:59:10

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:59:08', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '571484b1-dbea-46bd-ae03-5258f9ef31c8' User entered '17 Aug 2020 21:59'	System	18 Aug 2020 02:59:10
	System	18 Aug 2020 02:59:10

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Aug 2020 18:44'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:01:54



US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 2'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:42:05', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f6a296c7-6ab7-41be-9367-1553192f1d5f' User entered 'Yes (Y)'	System	18 Aug 2020 17:42:59
	System	18 Aug 2020 17:42:59

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:42:48', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f6a296c7-6ab7-41be-9367-1553192f1d5f' User entered '98.3'	System	18 Aug 2020 17:42:59
	System	18 Aug 2020 17:42:59

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:42:53', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f6a296c7-6ab7-41be-9367-1553192f1d5f' User entered 'No (N)'	System	18 Aug 2020 17:42:59
	System	18 Aug 2020 17:42:59

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:42:56', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f6a296c7-6ab7-41be-9367-1553192f1d5f' User entered '18 Aug 2020 12:42'	System	18 Aug 2020 17:42:59
	System	18 Aug 2020 17:42:59

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 3'	System	17 Aug 2020 20:01:54



US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:54:34', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '03e6e7e4-ae01-48ca-bc74-d513815a917f' User entered 'Yes (Y)'	System	20 Aug 2020 01:54:53
	System	20 Aug 2020 01:54:53

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:54:45', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '03e6e7e4-ae01-48ca-bc74-d513815a917f' User entered '97.9'	System	20 Aug 2020 01:54:53
	System	20 Aug 2020 01:54:53

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:54:48', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '03e6e7e4-ae01-48ca-bc74-d513815a917f' User entered 'No (N)'	System	20 Aug 2020 01:54:53
	System	20 Aug 2020 01:54:53

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:54:50', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '03e6e7e4-ae01-48ca-bc74-d513815a917f' User entered '19 Aug 2020 20:54'	System	20 Aug 2020 01:54:53
	System	20 Aug 2020 01:54:53

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 4'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:12:01', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94b6a69d-561f-4bd0-989c-deb4d4ed7ca6' User entered 'Yes (Y)'	System	21 Aug 2020 09:21:07
	System	21 Aug 2020 09:21:07



US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:12:09', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94b6a69d-561f-4bd0-989c-deb4d4ed7ca6' User entered '98.2'	System	21 Aug 2020 09:21:07
	System	21 Aug 2020 09:21:07

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:12:11', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94b6a69d-561f-4bd0-989c-deb4d4ed7ca6'	System	21 Aug 2020 09:21:07
User entered 'No (N)'	System	21 Aug 2020 09:21:07

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:12:13', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94b6a69d-561f-4bd0-989c-deb4d4ed7ca6' User entered '20 Aug 2020 13:12'	System	21 Aug 2020 09:21:07
	System	21 Aug 2020 09:21:07

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 5'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:36:14', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '86f3446b-a80f-4b8a-affd-dd0de4ec3377'	System	22 Aug 2020 00:38:39
User entered 'Yes (Y)'	System	22 Aug 2020 00:38:39

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:38:32', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '86f3446b-a80f-4b8a-affd-dd0de4ec3377'	System	22 Aug 2020 00:38:39
User entered '98.1'	System	22 Aug 2020 00:38:39



US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:38:34', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '86f3446b-a80f-4b8a-affd-dd0de4ec3377'	System	22 Aug 2020 00:38:39
User entered 'No (N)'	System	22 Aug 2020 00:38:39

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:38:36', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '86f3446b-a80f-4b8a-affd-dd0de4ec3377'	System	22 Aug 2020 00:38:39
User entered '21 Aug 2020 19:38'	System	22 Aug 2020 00:38:39

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 6'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:33', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '1ff5d1a8-9706-4ff4-8a72-7db20be3b6ca' User entered 'Yes (Y)'	System	23 Aug 2020 03:28:44
	System	23 Aug 2020 03:28:44

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:37', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '1ff5d1a8-9706-4ff4-8a72-7db20be3b6ca' User entered '98.2'	System	23 Aug 2020 03:28:44
	System	23 Aug 2020 03:28:44

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:40', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '1ff5d1a8-9706-4ff4-8a72-7db20be3b6ca' User entered 'No (N)'	System	23 Aug 2020 03:28:44
	System	23 Aug 2020 03:28:44



US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:42', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '1ff5d1a8-9706-4ff4-8a72-7db20be3b6ca' User entered '22 Aug 2020 22:28'	System	23 Aug 2020 03:28:44
	System	23 Aug 2020 03:28:44

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 7'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:56:28', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a20cbe26-4144-4450-8bc4-6bd6f46aab31' User entered 'Yes (Y)'	System	24 Aug 2020 03:56:42
	System	24 Aug 2020 03:56:42

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:56:35', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a20cbe26-4144-4450-8bc4-6bd6f46aab31' User entered '98.4'	System	24 Aug 2020 03:56:42
	System	24 Aug 2020 03:56:42

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:56:38', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a20cbe26-4144-4450-8bc4-6bd6f46aab31' User entered 'No (N)'	System	24 Aug 2020 03:56:42
	System	24 Aug 2020 03:56:42

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:56:40', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a20cbe26-4144-4450-8bc4-6bd6f46aab31' User entered '23 Aug 2020 22:56'	System	24 Aug 2020 03:56:42
	System	24 Aug 2020 03:56:42



US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:31:35', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '50c10aa3-8d66-49e0-98bb-d3f10fdafb37'	System	17 Aug 2020 20:32:08
User entered 'None (1)'	System	17 Aug 2020 20:32:08

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:31:39', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '50c10aa3-8d66-49e0-98bb-d3f10fdafb37'	System	17 Aug 2020 20:32:08
User entered 'No (N)'	System	17 Aug 2020 20:32:08

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:31:44', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '50c10aa3-8d66-49e0-98bb-d3f10fdafb37'	System	17 Aug 2020 20:32:08
User entered 'No (N)'	System	17 Aug 2020 20:32:08

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:01', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '50c10aa3-8d66-49e0-98bb-d3f10fdafb37'	System	17 Aug 2020 20:32:08
User entered 'None (1)'	System	17 Aug 2020 20:32:08

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:05', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '50c10aa3-8d66-49e0-98bb-d3f10fdafb37'	System	17 Aug 2020 20:32:08
User entered '17 Aug 2020 15:32'	System	17 Aug 2020 20:32:08



US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Aug 2020 15:19'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Aug 2020 17:49'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:53:29', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '599e58d6-88f9-4bcb-a04d-3b3ed8d42317' User entered 'None (1)'	System	18 Aug 2020 02:53:48
	System	18 Aug 2020 02:53:48

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:53:32', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '599e58d6-88f9-4bcb-a04d-3b3ed8d42317'	System	18 Aug 2020 02:53:48
User entered 'No (N)'	System	18 Aug 2020 02:53:48

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:53:35', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '599e58d6-88f9-4bcb-a04d-3b3ed8d42317' User entered 'No (N)'	System	18 Aug 2020 02:53:48
	System	18 Aug 2020 02:53:48

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:53:40', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '599e58d6-88f9-4bcb-a04d-3b3ed8d42317' User entered 'None (1)'	System	18 Aug 2020 02:53:48
	System	18 Aug 2020 02:53:48

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:53:44', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '599e58d6-88f9-4bcb-a04d-3b3ed8d42317' User entered '17 Aug 2020 21:53'	System	18 Aug 2020 02:53:48
	System	18 Aug 2020 02:53:48



US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Aug 2020 18:44'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 2'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:40:39', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '59a1f46f-0e07-4352-80cb-4867a3c25207'	System	18 Aug 2020 17:40:57
User entered 'None (1)'	System	18 Aug 2020 17:40:57

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:40:42', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '59a1f46f-0e07-4352-80cb-4867a3c25207'	System	18 Aug 2020 17:40:57
User entered 'No (N)'	System	18 Aug 2020 17:40:57

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:40:45', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '59a1f46f-0e07-4352-80cb-4867a3c25207'	System	18 Aug 2020 17:40:57
User entered 'No (N)'	System	18 Aug 2020 17:40:57

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:40:51', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '59a1f46f-0e07-4352-80cb-4867a3c25207'	System	18 Aug 2020 17:40:57
User entered 'None (1)'	System	18 Aug 2020 17:40:57

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:40:53', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '59a1f46f-0e07-4352-80cb-4867a3c25207'	System	18 Aug 2020 17:40:57
User entered '18 Aug 2020 12:40'	System	18 Aug 2020 17:40:57



US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 3'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:23:52', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3f839a20-a41c-4d5c-8e5f-899bf31e43a8'	System	20 Aug 2020 01:24:06
User entered 'None (1)'	System	20 Aug 2020 01:24:06

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:23:54', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3f839a20-a41c-4d5c-8e5f-899bf31e43a8'	System	20 Aug 2020 01:24:06
User entered 'No (N)'	System	20 Aug 2020 01:24:06

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:23:57', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3f839a20-a41c-4d5c-8e5f-899bf31e43a8'	System	20 Aug 2020 01:24:06
User entered 'No (N)'	System	20 Aug 2020 01:24:06

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:23:59', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3f839a20-a41c-4d5c-8e5f-899bf31e43a8'	System	20 Aug 2020 01:24:06
User entered 'None (1)'	System	20 Aug 2020 01:24:06

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:24:01', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3f839a20-a41c-4d5c-8e5f-899bf31e43a8' User entered '19 Aug 2020 20:24'	System	20 Aug 2020 01:24:06
	System	20 Aug 2020 01:24:06



US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 4'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:29', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2fd93cd3-c732-4437-a4c9-091d415b2040' User entered 'None (1)'	System	20 Aug 2020 18:11:41
	System	20 Aug 2020 18:11:41

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:31', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2fd93cd3-c732-4437-a4c9-091d415b2040' User entered 'No (N)'	System	20 Aug 2020 18:11:41
	System	20 Aug 2020 18:11:41

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:33', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2fd93cd3-c732-4437-a4c9-091d415b2040' User entered 'No (N)'	System	20 Aug 2020 18:11:41
	System	20 Aug 2020 18:11:41

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:35', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2fd93cd3-c732-4437-a4c9-091d415b2040' User entered 'None (1)'	System	20 Aug 2020 18:11:41
	System	20 Aug 2020 18:11:41

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:37', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2fd93cd3-c732-4437-a4c9-091d415b2040' User entered '20 Aug 2020 13:11'	System	20 Aug 2020 18:11:41
	System	20 Aug 2020 18:11:41



US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 5'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:35:05', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '76d0b871-a892-4bad-863f-966e0fe74a0a' User entered 'None (1)'	System	22 Aug 2020 00:35:31
	System	22 Aug 2020 00:35:31

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:35:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '76d0b871-a892-4bad-863f-966e0fe74a0a' User entered 'No (N)'	System	22 Aug 2020 00:35:31
	System	22 Aug 2020 00:35:31

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:35:13', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '76d0b871-a892-4bad-863f-966e0fe74a0a' User entered 'No (N)'	System	22 Aug 2020 00:35:31
	System	22 Aug 2020 00:35:31

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:35:26', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '76d0b871-a892-4bad-863f-966e0fe74a0a' User entered 'None (1)'	System	22 Aug 2020 00:35:31
	System	22 Aug 2020 00:35:31

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:35:28', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '76d0b871-a892-4bad-863f-966e0fe74a0a' User entered '21 Aug 2020 19:35'	System	22 Aug 2020 00:35:31
	System	22 Aug 2020 00:35:31



US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 6'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:13', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6a5af699-2501-4535-83ea-6f3424597513'	System	23 Aug 2020 03:28:28
User entered 'None (1)'	System	23 Aug 2020 03:28:28

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:16', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6a5af699-2501-4535-83ea-6f3424597513'	System	23 Aug 2020 03:28:28
User entered 'No (N)'	System	23 Aug 2020 03:28:28

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:20', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6a5af699-2501-4535-83ea-6f3424597513'	System	23 Aug 2020 03:28:28
User entered 'No (N)'	System	23 Aug 2020 03:28:28

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:23', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6a5af699-2501-4535-83ea-6f3424597513'	System	23 Aug 2020 03:28:28
User entered 'None (1)'	System	23 Aug 2020 03:28:28

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:25', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6a5af699-2501-4535-83ea-6f3424597513' User entered '22 Aug 2020 22:28'	System	23 Aug 2020 03:28:28
	System	23 Aug 2020 03:28:28



US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 7'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:56:13', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '5c72aea4-b60e-446c-b088-d26cc9551f4f' User entered 'None (1)'	System	24 Aug 2020 03:56:26
	System	24 Aug 2020 03:56:26

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:56:16', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '5c72aea4-b60e-446c-b088-d26cc9551f4f' User entered 'No (N)'	System	24 Aug 2020 03:56:26
	System	24 Aug 2020 03:56:26

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:56:18', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '5c72aea4-b60e-446c-b088-d26cc9551f4f' User entered 'No (N)'	System	24 Aug 2020 03:56:26
	System	24 Aug 2020 03:56:26

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:56:20', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '5c72aea4-b60e-446c-b088-d26cc9551f4f' User entered 'None (1)'	System	24 Aug 2020 03:56:26
	System	24 Aug 2020 03:56:26

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:56:22', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '5c72aea4-b60e-446c-b088-d26cc9551f4f' User entered '23 Aug 2020 22:56'	System	24 Aug 2020 03:56:26
	System	24 Aug 2020 03:56:26



US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:16', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94dda98b-5fce-4f7a-a8b6-1f4c90c24cb6' User entered 'None (0)'	System	17 Aug 2020 20:33:04
	System	17 Aug 2020 20:33:04

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:35', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94dda98b-5fce-4f7a-a8b6-1f4c90c24cb6' User entered 'None (0)'	System	17 Aug 2020 20:33:04
	System	17 Aug 2020 20:33:04

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:38', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94dda98b-5fce-4f7a-a8b6-1f4c90c24cb6' User entered 'None (0)'	System	17 Aug 2020 20:33:04
	System	17 Aug 2020 20:33:04

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:42', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94dda98b-5fce-4f7a-a8b6-1f4c90c24cb6' User entered 'None (0)'	System	17 Aug 2020 20:33:04
	System	17 Aug 2020 20:33:04

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:46', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94dda98b-5fce-4f7a-a8b6-1f4c90c24cb6' User entered 'None (0)'	System	17 Aug 2020 20:33:04
	System	17 Aug 2020 20:33:04



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:50', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94dda98b-5fce-4f7a-a8b6-1f4c90c24cb6' User entered 'None (0)'	System	17 Aug 2020 20:33:04
	System	17 Aug 2020 20:33:04

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:57', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94dda98b-5fce-4f7a-a8b6-1f4c90c24cb6' User entered 'No (N)'	System	17 Aug 2020 20:33:04
	System	17 Aug 2020 20:33:04

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T15:32:59', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94dda98b-5fce-4f7a-a8b6-1f4c90c24cb6' User entered '17 Aug 2020 15:32'	System	17 Aug 2020 20:33:04
	System	17 Aug 2020 20:33:04

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Aug 2020 15:19'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Aug 2020 17:49'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:53:53', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '13cc5c79-d392-4c70-9dad-fdcccfdcdc702'	System	18 Aug 2020 02:54:24
User entered 'No interference with activity (1)'	System	18 Aug 2020 02:54:24

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:54:01', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '13cc5c79-d392-4c70-9dad-fdcccfdcdc702'	System	18 Aug 2020 02:54:24
User entered 'No interference with activity (1)'	System	18 Aug 2020 02:54:24



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:54:04', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '13cc5c79-d392-4c70-9dad-fdcccfdcdc702' User entered 'None (0)'	System	18 Aug 2020 02:54:24
	System	18 Aug 2020 02:54:24

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:54:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '13cc5c79-d392-4c70-9dad-fdcccfdcdc702' User entered 'None (0)'	System	18 Aug 2020 02:54:24
	System	18 Aug 2020 02:54:24

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:54:10', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '13cc5c79-d392-4c70-9dad-fdcccfdcdc702' User entered 'None (0)'	System	18 Aug 2020 02:54:24
	System	18 Aug 2020 02:54:24

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:54:13', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '13cc5c79-d392-4c70-9dad-fdcccfdcdc702' User entered 'None (0)'	System	18 Aug 2020 02:54:24
	System	18 Aug 2020 02:54:24

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:54:18', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '13cc5c79-d392-4c70-9dad-fdcccfdcdc702'	System	18 Aug 2020 02:54:24
User entered 'No (N)'	System	18 Aug 2020 02:54:24

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-17T21:54:22', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '13cc5c79-d392-4c70-9dad-fdcccfdcdc702' User entered '17 Aug 2020 21:54'	System	18 Aug 2020 02:54:24
	System	18 Aug 2020 02:54:24

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Aug 2020 18:44'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:01:54



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 2'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:41:02', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '334fcde4-11ad-4c5c-bd85-727820c629da' User entered 'None (0)'	System	18 Aug 2020 17:41:37
	System	18 Aug 2020 17:41:37

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:41:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '334fcde4-11ad-4c5c-bd85-727820c629da' User entered 'None (0)'	System	18 Aug 2020 17:41:37
	System	18 Aug 2020 17:41:37

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:41:09', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '334fcde4-11ad-4c5c-bd85-727820c629da' User entered 'None (0)'	System	18 Aug 2020 17:41:37
	System	18 Aug 2020 17:41:37

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:41:16', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '334fcde4-11ad-4c5c-bd85-727820c629da' User entered 'None (0)'	System	18 Aug 2020 17:41:37
	System	18 Aug 2020 17:41:37

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:41:18', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '334fcde4-11ad-4c5c-bd85-727820c629da' User entered 'None (0)'	System	18 Aug 2020 17:41:37
	System	18 Aug 2020 17:41:37

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:41:20', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '334fcde4-11ad-4c5c-bd85-727820c629da' User entered 'None (0)'	System	18 Aug 2020 17:41:37
	System	18 Aug 2020 17:41:37

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:41:23', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '334fcde4-11ad-4c5c-bd85-727820c629da' User entered 'No (N)'	System	18 Aug 2020 17:41:37
	System	18 Aug 2020 17:41:37



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-18T12:41:26', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '334fcde4-11ad-4c5c-bd85-727820c629da' User entered '18 Aug 2020 12:41'	System	18 Aug 2020 17:41:37
	System	18 Aug 2020 17:41:37

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 3'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:24:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '8789d96d-8c0b-4224-8b1c-a013c2d6edd2' User entered 'None (0)'	System	20 Aug 2020 01:24:31
	System	20 Aug 2020 01:24:31

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:24:10', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '8789d96d-8c0b-4224-8b1c-a013c2d6edd2' User entered 'None (0)'	System	20 Aug 2020 01:24:31
	System	20 Aug 2020 01:24:31

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:24:13', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '8789d96d-8c0b-4224-8b1c-a013c2d6edd2' User entered 'None (0)'	System	20 Aug 2020 01:24:31
	System	20 Aug 2020 01:24:31

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:24:16', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '8789d96d-8c0b-4224-8b1c-a013c2d6edd2' User entered 'None (0)'	System	20 Aug 2020 01:24:31
	System	20 Aug 2020 01:24:31



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:24:18', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '8789d96d-8c0b-4224-8b1c-a013c2d6edd2' User entered 'None (0)'	System	20 Aug 2020 01:24:31
	System	20 Aug 2020 01:24:31

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:24:20', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '8789d96d-8c0b-4224-8b1c-a013c2d6edd2' User entered 'None (0)'	System	20 Aug 2020 01:24:31
	System	20 Aug 2020 01:24:31

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:24:23', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '8789d96d-8c0b-4224-8b1c-a013c2d6edd2' User entered 'No (N)'	System	20 Aug 2020 01:24:31
	System	20 Aug 2020 01:24:31

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-19T20:24:27', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '8789d96d-8c0b-4224-8b1c-a013c2d6edd2' User entered '19 Aug 2020 20:24'	System	20 Aug 2020 01:24:31
	System	20 Aug 2020 01:24:31

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 4'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:40', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '779658bb-a4a7-4ec6-9126-12bed13ec947' User entered 'None (0)'	System	20 Aug 2020 18:11:57
	System	20 Aug 2020 18:11:57



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:42', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '779658bb-a4a7-4ec6-9126-12bed13ec947' User entered 'None (0)'	System	20 Aug 2020 18:11:57
	System	20 Aug 2020 18:11:57

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:43', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '779658bb-a4a7-4ec6-9126-12bed13ec947' User entered 'None (0)'	System	20 Aug 2020 18:11:57
	System	20 Aug 2020 18:11:57

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:45', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '779658bb-a4a7-4ec6-9126-12bed13ec947' User entered 'None (0)'	System	20 Aug 2020 18:11:57
	System	20 Aug 2020 18:11:57

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:47', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '779658bb-a4a7-4ec6-9126-12bed13ec947' User entered 'None (0)'	System	20 Aug 2020 18:11:57
	System	20 Aug 2020 18:11:57

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:49', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '779658bb-a4a7-4ec6-9126-12bed13ec947' User entered 'None (0)'	System	20 Aug 2020 18:11:57
	System	20 Aug 2020 18:11:57

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:52', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '779658bb-a4a7-4ec6-9126-12bed13ec947' User entered 'No (N)'	System	20 Aug 2020 18:11:57
	System	20 Aug 2020 18:11:57

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-20T13:11:56', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '779658bb-a4a7-4ec6-9126-12bed13ec947' User entered '20 Aug 2020 13:11'	System	20 Aug 2020 18:11:57
	System	20 Aug 2020 18:11:57

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:01:54



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 5'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:34:37', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2bbaa81a-f820-4cb3-aa43-ff97b64e30be' User entered 'None (0)'	System	22 Aug 2020 00:35:06
	System	22 Aug 2020 00:35:06

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:34:38', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2bbaa81a-f820-4cb3-aa43-ff97b64e30be' User entered 'None (0)'	System	22 Aug 2020 00:35:06
	System	22 Aug 2020 00:35:06

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:34:40', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2bbaa81a-f820-4cb3-aa43-ff97b64e30be' User entered 'None (0)'	System	22 Aug 2020 00:35:06
	System	22 Aug 2020 00:35:06

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:34:42', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2bbaa81a-f820-4cb3-aa43-ff97b64e30be' User entered 'None (0)'	System	22 Aug 2020 00:35:06
	System	22 Aug 2020 00:35:06

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:34:44', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2bbaa81a-f820-4cb3-aa43-ff97b64e30be' User entered 'None (0)'	System	22 Aug 2020 00:35:06
	System	22 Aug 2020 00:35:06

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:34:46', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2bbaa81a-f820-4cb3-aa43-ff97b64e30be' User entered 'None (0)'	System	22 Aug 2020 00:35:06
	System	22 Aug 2020 00:35:06



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:34:48', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2bbaa81a-f820-4cb3-aa43-ff97b64e30be' User entered 'No (N)'	System	22 Aug 2020 00:35:06
	System	22 Aug 2020 00:35:06

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-21T19:35:02', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2bbaa81a-f820-4cb3-aa43-ff97b64e30be' User entered '21 Aug 2020 19:35'	System	22 Aug 2020 00:35:06
	System	22 Aug 2020 00:35:06

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 6'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:27:50', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3646f331-8c58-43c0-9603-064278229fba' User entered 'None (0)'	System	23 Aug 2020 03:28:12
	System	23 Aug 2020 03:28:12

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:27:53', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3646f331-8c58-43c0-9603-064278229fba' User entered 'None (0)'	System	23 Aug 2020 03:28:12
	System	23 Aug 2020 03:28:12

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:27:55', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3646f331-8c58-43c0-9603-064278229fba' User entered 'None (0)'	System	23 Aug 2020 03:28:12
	System	23 Aug 2020 03:28:12



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:27:57', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3646f331-8c58-43c0-9603-064278229fba' User entered 'None (0)'	System	23 Aug 2020 03:28:12
	System	23 Aug 2020 03:28:12

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3646f331-8c58-43c0-9603-064278229fba' User entered 'None (0)'	System	23 Aug 2020 03:28:12
	System	23 Aug 2020 03:28:12

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:02', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3646f331-8c58-43c0-9603-064278229fba' User entered 'None (0)'	System	23 Aug 2020 03:28:12
	System	23 Aug 2020 03:28:12

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:05', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3646f331-8c58-43c0-9603-064278229fba' User entered 'No (N)'	System	23 Aug 2020 03:28:12
	System	23 Aug 2020 03:28:12

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-22T22:28:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3646f331-8c58-43c0-9603-064278229fba' User entered '22 Aug 2020 22:28'	System	23 Aug 2020 03:28:12
	System	23 Aug 2020 03:28:12

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 7'	System	17 Aug 2020 20:01:54



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:55:39', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f880e75-aa04-450f-ba71-002c677ce5f7' User entered 'None (0)'	System	24 Aug 2020 03:55:55
	System	24 Aug 2020 03:55:55

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:55:40', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f880e75-aa04-450f-ba71-002c677ce5f7'	System	24 Aug 2020 03:55:55
User entered 'None (0)'	System	24 Aug 2020 03:55:55

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:55:42', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f880e75-aa04-450f-ba71-002c677ce5f7' User entered 'None (0)'	System	24 Aug 2020 03:55:55
	System	24 Aug 2020 03:55:55

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:55:44', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f880e75-aa04-450f-ba71-002c677ce5f7' User entered 'None (0)'	System	24 Aug 2020 03:55:55
	System	24 Aug 2020 03:55:55

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:55:46', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f880e75-aa04-450f-ba71-002c677ce5f7' User entered 'None (0)'	System	24 Aug 2020 03:55:55
	System	24 Aug 2020 03:55:55

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:55:48', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f880e75-aa04-450f-ba71-002c677ce5f7'	System	24 Aug 2020 03:55:55
User entered 'None (0)'	System	24 Aug 2020 03:55:55

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:55:52', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f880e75-aa04-450f-ba71-002c677ce5f7' User entered 'No (N)'	System	24 Aug 2020 03:55:55
	System	24 Aug 2020 03:55:55

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-08-23T22:55:54', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f880e75-aa04-450f-ba71-002c677ce5f7' User entered '23 Aug 2020 22:55'	System	24 Aug 2020 03:55:55
	System	24 Aug 2020 03:55:55



US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:01:54

US3342085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	24 Aug 2020 20:28:07

US3342085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '24 Aug 2020'	Ethan Shotton (b) (4)	24 Aug 2020 20:28:07

US3342085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	24 Aug 2020 20:28:07

US3342085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	Ethan Shotton (b) (4)	24 Aug 2020 20:28:07

US3342085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	24 Aug 2020 20:28:11

US3342085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '1'	System	24 Aug 2020 20:28:11



US3342085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	31 Aug 2020 16:14:36

US3342085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '31 Aug 2020'	Ethan Shotton (b) (4)	31 Aug 2020 16:14:36

US3342085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	31 Aug 2020 16:14:36

US3342085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	Ethan Shotton (b) (4)	31 Aug 2020 16:14:36

US3342085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	31 Aug 2020 16:14:40

US3342085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'I'	System	31 Aug 2020 16:14:40

US3342085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	08 Sep 2020 23:25:44

US3342085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '8 Sep 2020'	Ethan Shotton (b) (4)	08 Sep 2020 23:25:44



US3342085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	08 Sep 2020 23:25:44

US3342085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	Ethan Shotton (b) (4)	08 Sep 2020 23:25:44

US3342085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	08 Sep 2020 23:25:47

US3342085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'I'	System	08 Sep 2020 23:25:47

US3342085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:13:43

US3342085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:13:43

US3342085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	16 Sep 2020 21:13:43

US3342085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'VISIT2'	System	16 Sep 2020 21:13:43



US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Schulle (b) (4) (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '15:28'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '16 Sep 2020 15:28'	System	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '99.3' F	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Oral (Oral)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41



US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '118'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'bpm'	System	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'breaths/min'	System	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '130'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '84'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	16 Sep 2020 21:14:41



US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Schulle (b) (4) (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 21:31:06
Query 'Data is required. Please provide.' answered by System	System	16 Sep 2020 21:31:06
data change (Site from System).		
User entered '16:38' reason for change: Data Entry	(b) (4), (b) (6)	16 Sep 2020 21:31:06
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 21:14:41
User entered empty.	Morgan Schulle (b) (4)	16 Sep 2020 21:14:41
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '16 Sep 2020 16:38'	System	16 Sep 2020 21:31:06
User entered empty.	System	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 21:41:24
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 21:41:24
User entered '99.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:41:24
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 21:14:41
User entered empty.	Morgan Schulle (b) (4)	16 Sep 2020 21:14:41
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:41:24
User entered empty.	Morgan Schulle (b) (4) (b) (4)	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:41



US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 21:41:24
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 21:41:24
User entered '109' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:41:24
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 21:14:41
User entered empty.	Morgan Schulle (b) (4)	16 Sep 2020 21:14:41
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'bpm'	System	16 Sep 2020 21:41:24
User entered empty.	System	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 21:41:24
Query 'Data is required. Please provide.' answered by System	System	16 Sep 2020 21:41:24
data change (Site from System).		
User entered '16' reason for change: Data Entry	(b) (4), (b) (6)	16 Sep 2020 21:41:24
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 21:14:41
User entered empty.	Morgan Schulle (b) (4)	16 Sep 2020 21:14:41
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'breaths/min'	System	16 Sep 2020 21:41:24
User entered empty.	System	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 21:41:24
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	16 Sep 2020 21:41:24
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 21:41:24
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 21:14:41
User entered empty.	Morgan Schulle (b) (4)	16 Sep 2020 21:14:41
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	16 Sep 2020 21:41:24
User entered empty.	System	16 Sep 2020 21:14:41

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 21:41:24
Query 'Data is required. Please provide.' answered by System	System	16 Sep 2020 21:41:24
data change (Site from System).		
User entered '84' reason for change: Data Entry	(b) (4), (b) (6)	16 Sep 2020 21:41:24
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 21:14:41
User entered empty.	Morgan Schulle (b) (4)	16 Sep 2020 21:14:41
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	16 Sep 2020 21:41:24
User entered empty.	System	16 Sep 2020 21:14:41



US3342085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:14:48

US3342085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4)	
	Morgan Schulle (b) (4)	16 Sep 2020 21:14:48
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:17:40

US3342085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:17:40

US3342085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Urine (URINE)'	Morgan Schulle (b) (4)	16 Sep 2020 21:17:40

US3342085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Negative (NEGATIVE)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:17:40

US3342085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:17:40

US3342085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:17:40



US3342085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4)	
	Morgan Schulle (b) (4)	16 Sep 2020 21:17:40
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered empty.	System	16 Sep 2020 21:17:40

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	16 Sep 2020 21:26:48
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	16 Sep 2020 21:26:48
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	16 Sep 2020 21:17:48
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	16 Sep 2020 21:17:48
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4)	
	Morgan Schulle (b) (4)	16 Sep 2020 21:17:48
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

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)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	Morgan Schulle (b) (4)	16 Sep 2020 21:17:48

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 21:17:48

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:17:48

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16:07' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:26:48
User entered empty.	Morgan Schulle (b) (4) (b) (4)	16 Sep 2020 21:17:48



US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '16 Sep 2020 16:07'	System	16 Sep 2020 21:26:48
User entered empty.	System	16 Sep 2020 21:17:48

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Sep 2020 21:26:48
User entered empty.	Morgan Schulle (b) (4) (b) (4)	16 Sep 2020 21:17:48

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'ONCE'	System	16 Sep 2020 21:17:48

US3342085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 21:17:48

US3342085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:17:55

US3342085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16 Sep 2020'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:17:55

US3342085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	16 Sep 2020 21:48:28
User entered '15:49' reason for change: Data Entry Error	System	16 Sep 2020 21:48:28
User opened query 'Data is required. Please provide.' (Site from System).	Morgan Schulle (b) (4)	16 Sep 2020 21:48:28
User entered empty.	(b) (4)	16 Sep 2020 21:48:28
	System	16 Sep 2020 21:17:55
	Morgan Schulle (b) (4)	16 Sep 2020 21:17:55
	(b) (4)	16 Sep 2020 21:17:55

US3342085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '16 Sep 2020 15:49'	System	16 Sep 2020 21:48:28
User entered empty.	System	16 Sep 2020 21:17:55



US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16 Sep 2020'	Morgan Schulle (b) (4)	16 Sep 2020 21:18:03

US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	16 Sep 2020 21:18:03

US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:18:03

US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	16 Sep 2020 21:48:18
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	16 Sep 2020 21:48:18
User entered '15:52' reason for change: Data Entry Error	Morgan Schulle (b) (4)	16 Sep 2020 21:48:18
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	16 Sep 2020 21:18:03
User entered empty.	System	16 Sep 2020 21:18:03
	Morgan Schulle (b) (4)	16 Sep 2020 21:18:03
	(b) (4)	

US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '16 Sep 2020 15:52'	System	16 Sep 2020 21:48:18
User entered empty.	System	16 Sep 2020 21:18:03

US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	16 Sep 2020 21:18:03

US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	Morgan Schulle (b) (4)	16 Sep 2020 21:18:03

US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:18:03



US3342085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered empty.	System	16 Sep 2020 21:18:03

US3342085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	16 Sep 2020 21:18:07

US3342085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '1'	System	16 Sep 2020 21:18:07

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:41:46', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '087782fd-21d2-45fe-acf3-9a5a390c741e' User entered 'Yes (Y)'	System	16 Sep 2020 21:42:04
	System	16 Sep 2020 21:42:04

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:41:51', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '087782fd-21d2-45fe-acf3-9a5a390c741e' User entered '99.2'	System	16 Sep 2020 21:42:04
	System	16 Sep 2020 21:42:04

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:41:55', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '087782fd-21d2-45fe-acf3-9a5a390c741e' User entered 'No (N)'	System	16 Sep 2020 21:42:04
	System	16 Sep 2020 21:42:04

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:41:59', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '087782fd-21d2-45fe-acf3-9a5a390c741e' User entered '16 Sep 2020 16:41'	System	16 Sep 2020 21:42:04
	System	16 Sep 2020 21:42:04



US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '16 Sep 2020 16:27'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '16 Sep 2020 18:57'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:41:05', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a58a11d4-3066-4735-9bd6-20cacdb7de25' User entered 'Yes (Y)'	System	17 Sep 2020 08:41:48
	System	17 Sep 2020 08:41:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:41:31', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a58a11d4-3066-4735-9bd6-20cacdb7de25' User entered '98.2'	System	17 Sep 2020 08:41:48
	System	17 Sep 2020 08:41:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:41:40', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a58a11d4-3066-4735-9bd6-20cacdb7de25'	System	17 Sep 2020 08:41:48
User entered 'No (N)'	System	17 Sep 2020 08:41:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:41:45', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a58a11d4-3066-4735-9bd6-20cacdb7de25' User entered '17 Sep 2020 03:41'	System	17 Sep 2020 08:41:48
	System	17 Sep 2020 08:41:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '16 Sep 2020 19:52'	System	16 Sep 2020 21:26:48



US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 2'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:10:48', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c3b92847-0ebd-4c29-baff-bab563f3f391' User entered 'Yes (Y)'	System	17 Sep 2020 18:11:01
	System	17 Sep 2020 18:11:01

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:10:54', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c3b92847-0ebd-4c29-baff-bab563f3f391' User entered '98.2'	System	17 Sep 2020 18:11:01
	System	17 Sep 2020 18:11:01

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:10:56', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c3b92847-0ebd-4c29-baff-bab563f3f391' User entered 'No (N)'	System	17 Sep 2020 18:11:01
	System	17 Sep 2020 18:11:01

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:10:58', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c3b92847-0ebd-4c29-baff-bab563f3f391' User entered '17 Sep 2020 13:10'	System	17 Sep 2020 18:11:01
	System	17 Sep 2020 18:11:01

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 21:26:48



US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 3'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:17:48', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9cf2c8c5-6ff9-4cf8-b55d-a83972144fa0' User entered 'Yes (Y)'	System	19 Sep 2020 05:18:03
	System	19 Sep 2020 05:18:03

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:17:53', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9cf2c8c5-6ff9-4cf8-b55d-a83972144fa0' User entered '98.2'	System	19 Sep 2020 05:18:03
	System	19 Sep 2020 05:18:03

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:17:57', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9cf2c8c5-6ff9-4cf8-b55d-a83972144fa0'	System	19 Sep 2020 05:18:03
User entered 'No (N)'	System	19 Sep 2020 05:18:03

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9cf2c8c5-6ff9-4cf8-b55d-a83972144fa0' User entered '19 Sep 2020 00:18'	System	19 Sep 2020 05:18:03
	System	19 Sep 2020 05:18:03

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 4'	System	16 Sep 2020 21:26:48



US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:23', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94985e56-6717-4b41-bceb-377ad4178e3c' User entered 'Yes (Y)'	System	19 Sep 2020 23:43:33
	System	19 Sep 2020 23:43:33

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:26', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94985e56-6717-4b41-bceb-377ad4178e3c' User entered '99.1'	System	19 Sep 2020 23:43:33
	System	19 Sep 2020 23:43:33

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:28', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94985e56-6717-4b41-bceb-377ad4178e3c'	System	19 Sep 2020 23:43:33
User entered 'No (N)'	System	19 Sep 2020 23:43:33

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:31', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '94985e56-6717-4b41-bceb-377ad4178e3c' User entered '19 Sep 2020 18:43'	System	19 Sep 2020 23:43:33
	System	19 Sep 2020 23:43:33

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 5'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:06:44', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6e87e22c-3cfd-453d-8aa6-a81748de8b66' User entered 'Yes (Y)'	System	21 Sep 2020 02:07:27
	System	21 Sep 2020 02:07:27



US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:06:52', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6e87e22c-3cfd-453d-8aa6-a81748de8b66' User entered '98.6'	System	21 Sep 2020 02:07:27
	System	21 Sep 2020 02:07:27

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:20', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6e87e22c-3cfd-453d-8aa6-a81748de8b66'	System	21 Sep 2020 02:07:27
User entered 'No (N)'	System	21 Sep 2020 02:07:27

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:23', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6e87e22c-3cfd-453d-8aa6-a81748de8b66' User entered '20 Sep 2020 21:07'	System	21 Sep 2020 02:07:27
	System	21 Sep 2020 02:07:27

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 6'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:11', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '98ce67b7-9e7e-495f-9b1a-2122e7246228' User entered 'Yes (Y)'	System	22 Sep 2020 12:22:22
	System	22 Sep 2020 12:22:22

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:16', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '98ce67b7-9e7e-495f-9b1a-2122e7246228' User entered '98.1'	System	22 Sep 2020 12:22:22
	System	22 Sep 2020 12:22:22



US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:19', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '98ce67b7-9e7e-495f-9b1a-2122e7246228' User entered 'No (N)'	System	22 Sep 2020 12:22:22
	System	22 Sep 2020 12:22:22

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:21', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '98ce67b7-9e7e-495f-9b1a-2122e7246228' User entered '22 Sep 2020 07:22'	System	22 Sep 2020 12:22:22
	System	22 Sep 2020 12:22:22

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 7'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:21', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'b5c7a275-d309-47ad-840f-d2d2cf563e3e' User entered 'Yes (Y)'	System	23 Sep 2020 04:42:32
	System	23 Sep 2020 04:42:32

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:25', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'b5c7a275-d309-47ad-840f-d2d2cf563e3e' User entered '98.2'	System	23 Sep 2020 04:42:32
	System	23 Sep 2020 04:42:32

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:27', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'b5c7a275-d309-47ad-840f-d2d2cf563e3e' User entered 'No (N)'	System	23 Sep 2020 04:42:32
	System	23 Sep 2020 04:42:32



US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:30', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'b5c7a275-d309-47ad-840f-d2d2cf563e3e' User entered '22 Sep 2020 23:42'	System	23 Sep 2020 04:42:32
	System	23 Sep 2020 04:42:32

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:06', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2e02eb95-4088-4238-9400-4714952c6b92'	System	16 Sep 2020 21:42:24
User entered 'None (1)'	System	16 Sep 2020 21:42:24

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:11', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2e02eb95-4088-4238-9400-4714952c6b92'	System	16 Sep 2020 21:42:24
User entered 'No (N)'	System	16 Sep 2020 21:42:24

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:13', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2e02eb95-4088-4238-9400-4714952c6b92'	System	16 Sep 2020 21:42:24
User entered 'No (N)'	System	16 Sep 2020 21:42:24

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:18', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2e02eb95-4088-4238-9400-4714952c6b92'	System	16 Sep 2020 21:42:24
User entered 'None (1)'	System	16 Sep 2020 21:42:24



US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:20', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '2e02eb95-4088-4238-9400-4714952c6b92'	System	16 Sep 2020 21:42:24
User entered '16 Sep 2020 16:42'	System	16 Sep 2020 21:42:24

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '16 Sep 2020 16:27'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '16 Sep 2020 18:57'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:41:50', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd41a4f77-ecf5-46d6-82f7-0309f2940e7f'	System	17 Sep 2020 08:42:04
User entered 'None (1)'	System	17 Sep 2020 08:42:04

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:41:53', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd41a4f77-ecf5-46d6-82f7-0309f2940e7f' User entered 'No (N)'	System	17 Sep 2020 08:42:04
	System	17 Sep 2020 08:42:04

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:41:56', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd41a4f77-ecf5-46d6-82f7-0309f2940e7f' User entered 'No (N)'	System	17 Sep 2020 08:42:04
	System	17 Sep 2020 08:42:04

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:41:59', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd41a4f77-ecf5-46d6-82f7-0309f2940e7f' User entered 'None (1)'	System	17 Sep 2020 08:42:04
	System	17 Sep 2020 08:42:04



US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:42:01', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd41a4f77-ecf5-46d6-82f7-0309f2940e7f' User entered '17 Sep 2020 03:42'	System	17 Sep 2020 08:42:04
	System	17 Sep 2020 08:42:04

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '16 Sep 2020 19:52'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 2'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:03', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c9a1c610-5b7e-484a-9e62-d73aada1f472' User entered 'None (1)'	System	17 Sep 2020 18:11:18
	System	17 Sep 2020 18:11:18

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c9a1c610-5b7e-484a-9e62-d73aada1f472'	System	17 Sep 2020 18:11:18
User entered 'No (N)'	System	17 Sep 2020 18:11:18

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:10', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c9a1c610-5b7e-484a-9e62-d73aada1f472'	System	17 Sep 2020 18:11:18
User entered 'No (N)'	System	17 Sep 2020 18:11:18

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:12', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c9a1c610-5b7e-484a-9e62-d73aada1f472' User entered 'None (1)'	System	17 Sep 2020 18:11:18
	System	17 Sep 2020 18:11:18



US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:14', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c9a1c610-5b7e-484a-9e62-d73aada1f472'	System	17 Sep 2020 18:11:18
User entered '17 Sep 2020 13:11'	System	17 Sep 2020 18:11:18

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 3'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:05', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '95cd4011-0ebf-47dc-b643-165b148edd58' User entered 'None (1)'	System	19 Sep 2020 05:18:23
	System	19 Sep 2020 05:18:23

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:09', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '95cd4011-0ebf-47dc-b643-165b148edd58' User entered 'No (N)'	System	19 Sep 2020 05:18:23
	System	19 Sep 2020 05:18:23

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:14', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '95cd4011-0ebf-47dc-b643-165b148edd58' User entered 'No (N)'	System	19 Sep 2020 05:18:23
	System	19 Sep 2020 05:18:23

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:18', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '95cd4011-0ebf-47dc-b643-165b148edd58' User entered 'None (1)'	System	19 Sep 2020 05:18:23
	System	19 Sep 2020 05:18:23



US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:21', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '95cd4011-0ebf-47dc-b643-165b148edd58' User entered '19 Sep 2020 00:18'	System	19 Sep 2020 05:18:23
	System	19 Sep 2020 05:18:23

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 4'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:39', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd078a486-7ce2-4d28-90f7-68cf9b913401'	System	19 Sep 2020 23:43:50
User entered 'None (1)'	System	19 Sep 2020 23:43:50

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd078a486-7ce2-4d28-90f7-68cf9b913401' User entered 'No (N)'	System	19 Sep 2020 23:43:50
	System	19 Sep 2020 23:43:50

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:43', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd078a486-7ce2-4d28-90f7-68cf9b913401' User entered 'No (N)'	System	19 Sep 2020 23:43:50
	System	19 Sep 2020 23:43:50

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:46', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd078a486-7ce2-4d28-90f7-68cf9b913401'	System	19 Sep 2020 23:43:50
User entered 'None (1)'	System	19 Sep 2020 23:43:50



US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:48', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'd078a486-7ce2-4d28-90f7-68cf9b913401' User entered '19 Sep 2020 18:43'	System	19 Sep 2020 23:43:50
	System	19 Sep 2020 23:43:50

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 5'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:27', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '66d2e83d-d920-4e82-9f00-3f6156e60673' User entered 'None (1)'	System	21 Sep 2020 02:07:49
	System	21 Sep 2020 02:07:49

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:39', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '66d2e83d-d920-4e82-9f00-3f6156e60673' User entered 'No (N)'	System	21 Sep 2020 02:07:49
	System	21 Sep 2020 02:07:49

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '66d2e83d-d920-4e82-9f00-3f6156e60673' User entered 'No (N)'	System	21 Sep 2020 02:07:49
	System	21 Sep 2020 02:07:49

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:45', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '66d2e83d-d920-4e82-9f00-3f6156e60673' User entered 'None (1)'	System	21 Sep 2020 02:07:49
	System	21 Sep 2020 02:07:49



US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:47', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '66d2e83d-d920-4e82-9f00-3f6156e60673' User entered '20 Sep 2020 21:07'	System	21 Sep 2020 02:07:49
	System	21 Sep 2020 02:07:49

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 6'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:25', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a925f4a7-8837-4e66-8165-16035013ae2b' User entered 'None (1)'	System	22 Sep 2020 12:22:38
	System	22 Sep 2020 12:22:38

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:27', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a925f4a7-8837-4e66-8165-16035013ae2b' User entered 'No (N)'	System	22 Sep 2020 12:22:38
	System	22 Sep 2020 12:22:38

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:30', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a925f4a7-8837-4e66-8165-16035013ae2b' User entered 'No (N)'	System	22 Sep 2020 12:22:38
	System	22 Sep 2020 12:22:38

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:33', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a925f4a7-8837-4e66-8165-16035013ae2b' User entered 'None (1)'	System	22 Sep 2020 12:22:38
	System	22 Sep 2020 12:22:38



US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:35', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a925f4a7-8837-4e66-8165-16035013ae2b' User entered '22 Sep 2020 07:22'	System	22 Sep 2020 12:22:38
	System	22 Sep 2020 12:22:38

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 7'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:33', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'ec1c99d4-5f60-42fa-9d06-f510274ec884'	System	23 Sep 2020 04:42:45
User entered 'None (1)'	System	23 Sep 2020 04:42:45

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:35', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'ec1c99d4-5f60-42fa-9d06-f510274ec884' User entered 'No (N)'	System	23 Sep 2020 04:42:45
	System	23 Sep 2020 04:42:45

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:37', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'ec1c99d4-5f60-42fa-9d06-f510274ec884'	System	23 Sep 2020 04:42:45
User entered 'No (N)'	System	23 Sep 2020 04:42:45

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:40', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'ec1c99d4-5f60-42fa-9d06-f510274ec884'	System	23 Sep 2020 04:42:45
User entered 'None (1)'	System	23 Sep 2020 04:42:45



US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'ec1c99d4-5f60-42fa-9d06-f510274ec884'	System	23 Sep 2020 04:42:45
User entered '22 Sep 2020 23:42'	System	23 Sep 2020 04:42:45

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:26', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '129a8f2f-209f-4937-a88e-eb1e25b43144'	System	16 Sep 2020 21:42:54
User entered 'None (0)'	System	16 Sep 2020 21:42:54

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:32', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '129a8f2f-209f-4937-a88e-eb1e25b43144' User entered 'None (0)'	System	16 Sep 2020 21:42:54
	System	16 Sep 2020 21:42:54

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:34', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '129a8f2f-209f-4937-a88e-eb1e25b43144'	System	16 Sep 2020 21:42:54
User entered 'None (0)'	System	16 Sep 2020 21:42:54

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:36', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '129a8f2f-209f-4937-a88e-eb1e25b43144' User entered 'None (0)'	System	16 Sep 2020 21:42:54
	System	16 Sep 2020 21:42:54



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:39', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '129a8f2f-209f-4937-a88e-eb1e25b43144'	System	16 Sep 2020 21:42:54
User entered 'None (0)'	System	16 Sep 2020 21:42:54

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '129a8f2f-209f-4937-a88e-eb1e25b43144'	System	16 Sep 2020 21:42:54
User entered 'None (0)'	System	16 Sep 2020 21:42:54

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:48', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '129a8f2f-209f-4937-a88e-eb1e25b43144'	System	16 Sep 2020 21:42:54
User entered 'No (N)'	System	16 Sep 2020 21:42:54

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-16T16:42:50', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '129a8f2f-209f-4937-a88e-eb1e25b43144'	System	16 Sep 2020 21:42:54
User entered '16 Sep 2020 16:42'	System	16 Sep 2020 21:42:54

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '16 Sep 2020 16:27'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '16 Sep 2020 18:57'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:42:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '365706ad-fdd9-4c96-8c49-ef41cb0ec7b6' User entered 'None (0)'	System	17 Sep 2020 08:42:29
	System	17 Sep 2020 08:42:29



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:42:09', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '365706ad-fdd9-4c96-8c49-ef41cb0ec7b6' User entered 'None (0)'	System	17 Sep 2020 08:42:29
	System	17 Sep 2020 08:42:29

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:42:12', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '365706ad-fdd9-4c96-8c49-ef41cb0ec7b6' User entered 'None (0)'	System	17 Sep 2020 08:42:29
	System	17 Sep 2020 08:42:29

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:42:15', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '365706ad-fdd9-4c96-8c49-ef41cb0ec7b6' User entered 'None (0)'	System	17 Sep 2020 08:42:29
	System	17 Sep 2020 08:42:29

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:42:17', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '365706ad-fdd9-4c96-8c49-ef41cb0ec7b6' User entered 'None (0)'	System	17 Sep 2020 08:42:29
	System	17 Sep 2020 08:42:29

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:42:20', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '365706ad-fdd9-4c96-8c49-ef41cb0ec7b6' User entered 'None (0)'	System	17 Sep 2020 08:42:29
	System	17 Sep 2020 08:42:29

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:42:25', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '365706ad-fdd9-4c96-8c49-ef41cb0ec7b6' User entered 'No (N)'	System	17 Sep 2020 08:42:29
	System	17 Sep 2020 08:42:29

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T03:42:27', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '365706ad-fdd9-4c96-8c49-ef41cb0ec7b6' User entered '17 Sep 2020 03:42'	System	17 Sep 2020 08:42:29
	System	17 Sep 2020 08:42:29

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '16 Sep 2020 19:52'	System	16 Sep 2020 21:26:48



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 2'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:19', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4df997b1-787f-4a39-9a94-d191f708cfbd' User entered 'None (0)'	System	17 Sep 2020 18:13:38
	System	17 Sep 2020 18:13:38

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:30', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4df997b1-787f-4a39-9a94-d191f708cfbd' User entered 'None (0)'	System	17 Sep 2020 18:13:38
	System	17 Sep 2020 18:13:38

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:33', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4df997b1-787f-4a39-9a94-d191f708cfbd' User entered 'None (0)'	System	17 Sep 2020 18:13:38
	System	17 Sep 2020 18:13:38

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:35', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4df997b1-787f-4a39-9a94-d191f708cfbd' User entered 'None (0)'	System	17 Sep 2020 18:13:38
	System	17 Sep 2020 18:13:38

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:11:58', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4df997b1-787f-4a39-9a94-d191f708cfbd' User entered 'None (0)'	System	17 Sep 2020 18:13:38
	System	17 Sep 2020 18:13:38

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:12:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4df997b1-787f-4a39-9a94-d191f708cfbd' User entered 'None (0)'	System	17 Sep 2020 18:13:38
	System	17 Sep 2020 18:13:38



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:12:03', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4df997b1-787f-4a39-9a94-d191f708cfbd' User entered 'No (N)'	System	17 Sep 2020 18:13:38
	System	17 Sep 2020 18:13:38

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-17T13:12:28', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4df997b1-787f-4a39-9a94-d191f708cfbd' User entered '17 Sep 2020 13:12'	System	17 Sep 2020 18:13:38
	System	17 Sep 2020 18:13:38

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 3'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:26', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '843ba85c-137e-408b-bcc4-5ca7c2f0762b' User entered 'None (0)'	System	19 Sep 2020 05:18:53
	System	19 Sep 2020 05:18:53

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:29', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '843ba85c-137e-408b-bcc4-5ca7c2f0762b' User entered 'None (0)'	System	19 Sep 2020 05:18:53
	System	19 Sep 2020 05:18:53

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:31', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '843ba85c-137e-408b-bcc4-5ca7c2f0762b' User entered 'None (0)'	System	19 Sep 2020 05:18:53
	System	19 Sep 2020 05:18:53



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:34', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '843ba85c-137e-408b-bcc4-5ca7c2f0762b' User entered 'None (0)'	System	19 Sep 2020 05:18:53
	System	19 Sep 2020 05:18:53

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:36', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '843ba85c-137e-408b-bcc4-5ca7c2f0762b' User entered 'None (0)'	System	19 Sep 2020 05:18:53
	System	19 Sep 2020 05:18:53

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:39', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '843ba85c-137e-408b-bcc4-5ca7c2f0762b' User entered 'None (0)'	System	19 Sep 2020 05:18:53
	System	19 Sep 2020 05:18:53

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:46', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '843ba85c-137e-408b-bcc4-5ca7c2f0762b' User entered 'No (N)'	System	19 Sep 2020 05:18:53
	System	19 Sep 2020 05:18:53

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T00:18:49', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '843ba85c-137e-408b-bcc4-5ca7c2f0762b' User entered '19 Sep 2020 00:18'	System	19 Sep 2020 05:18:53
	System	19 Sep 2020 05:18:53

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 4'	System	16 Sep 2020 21:26:48



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:43:55', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '77e1c293-02a4-4fdf-a956-f0c90126066f' User entered 'No interference with activity (1)'	System	19 Sep 2020 23:44:21
	System	19 Sep 2020 23:44:21

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:44:02', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '77e1c293-02a4-4fdf-a956-f0c90126066f' User entered 'None (0)'	System	19 Sep 2020 23:44:21
	System	19 Sep 2020 23:44:21

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:44:05', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '77e1c293-02a4-4fdf-a956-f0c90126066f' User entered 'No interference with activity (1)'	System	19 Sep 2020 23:44:21
	System	19 Sep 2020 23:44:21

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:44:08', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '77e1c293-02a4-4fdf-a956-f0c90126066f' User entered 'No interference with activity (1)'	System	19 Sep 2020 23:44:21
	System	19 Sep 2020 23:44:21

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:44:11', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '77e1c293-02a4-4fdf-a956-f0c90126066f' User entered 'None (0)'	System	19 Sep 2020 23:44:21
	System	19 Sep 2020 23:44:21

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:44:13', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '77e1c293-02a4-4fdf-a956-f0c90126066f' User entered 'None (0)'	System	19 Sep 2020 23:44:21
	System	19 Sep 2020 23:44:21

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:44:16', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '77e1c293-02a4-4fdf-a956-f0c90126066f' User entered 'No (N)'	System	19 Sep 2020 23:44:21
	System	19 Sep 2020 23:44:21

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-19T18:44:18', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '77e1c293-02a4-4fdf-a956-f0c90126066f' User entered '19 Sep 2020 18:44'	System	19 Sep 2020 23:44:21
	System	19 Sep 2020 23:44:21



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 5'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:54', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '40f0e7b4-bf96-404e-a20d-9d296cc0778c' User entered 'None (0)'	System	21 Sep 2020 02:08:08
	System	21 Sep 2020 02:08:08

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:56', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '40f0e7b4-bf96-404e-a20d-9d296cc0778c' User entered 'None (0)'	System	21 Sep 2020 02:08:08
	System	21 Sep 2020 02:08:08

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:57', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '40f0e7b4-bf96-404e-a20d-9d296cc0778c' User entered 'None (0)'	System	21 Sep 2020 02:08:08
	System	21 Sep 2020 02:08:08

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:07:59', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '40f0e7b4-bf96-404e-a20d-9d296cc0778c' User entered 'None (0)'	System	21 Sep 2020 02:08:08
	System	21 Sep 2020 02:08:08

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:08:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '40f0e7b4-bf96-404e-a20d-9d296cc0778c' User entered 'None (0)'	System	21 Sep 2020 02:08:08
	System	21 Sep 2020 02:08:08



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:08:02', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '40f0e7b4-bf96-404e-a20d-9d296cc0778c' User entered 'None (0)'	System	21 Sep 2020 02:08:08
	System	21 Sep 2020 02:08:08

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:08:04', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '40f0e7b4-bf96-404e-a20d-9d296cc0778c' User entered 'No (N)'	System	21 Sep 2020 02:08:08
	System	21 Sep 2020 02:08:08

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-20T21:08:06', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '40f0e7b4-bf96-404e-a20d-9d296cc0778c' User entered '20 Sep 2020 21:08'	System	21 Sep 2020 02:08:08
	System	21 Sep 2020 02:08:08

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 6'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:38', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f4a2971-ecf1-4372-a78b-0c911c7e2641' User entered 'None (0)'	System	22 Sep 2020 12:23:12
	System	22 Sep 2020 12:23:12

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:40', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f4a2971-ecf1-4372-a78b-0c911c7e2641' User entered 'None (0)'	System	22 Sep 2020 12:23:12
	System	22 Sep 2020 12:23:12



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:43', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f4a2971-ecf1-4372-a78b-0c911c7e2641' User entered 'None (0)'	System	22 Sep 2020 12:23:12
	System	22 Sep 2020 12:23:12

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:45', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f4a2971-ecf1-4372-a78b-0c911c7e2641' User entered 'None (0)'	System	22 Sep 2020 12:23:12
	System	22 Sep 2020 12:23:12

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:47', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f4a2971-ecf1-4372-a78b-0c911c7e2641' User entered 'None (0)'	System	22 Sep 2020 12:23:12
	System	22 Sep 2020 12:23:12

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:50', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f4a2971-ecf1-4372-a78b-0c911c7e2641' User entered 'None (0)'	System	22 Sep 2020 12:23:12
	System	22 Sep 2020 12:23:12

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:53', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f4a2971-ecf1-4372-a78b-0c911c7e2641' User entered 'Yes (Y)'	System	22 Sep 2020 12:23:12
	System	22 Sep 2020 12:23:12

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T07:22:55', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6f4a2971-ecf1-4372-a78b-0c911c7e2641' User entered '22 Sep 2020 07:22'	System	22 Sep 2020 12:23:12
	System	22 Sep 2020 12:23:12

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 21:26:48



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	16 Sep 2020 21:26:48
User entered 'Day 7'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:45', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '12365a1a-54a9-48e2-8bb9-f6da810a0e90' User entered 'None (0)'	System	23 Sep 2020 04:43:05
	System	23 Sep 2020 04:43:05

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:47', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '12365a1a-54a9-48e2-8bb9-f6da810a0e90' User entered 'None (0)'	System	23 Sep 2020 04:43:05
	System	23 Sep 2020 04:43:05

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:49', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '12365a1a-54a9-48e2-8bb9-f6da810a0e90' User entered 'None (0)'	System	23 Sep 2020 04:43:05
	System	23 Sep 2020 04:43:05

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:51', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '12365a1a-54a9-48e2-8bb9-f6da810a0e90' User entered 'None (0)'	System	23 Sep 2020 04:43:05
	System	23 Sep 2020 04:43:05

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:54', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '12365a1a-54a9-48e2-8bb9-f6da810a0e90' User entered 'None (0)'	System	23 Sep 2020 04:43:05
	System	23 Sep 2020 04:43:05

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:42:56', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '12365a1a-54a9-48e2-8bb9-f6da810a0e90' User entered 'None (0)'	System	23 Sep 2020 04:43:05
	System	23 Sep 2020 04:43:05

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

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)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:43:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '12365a1a-54a9-48e2-8bb9-f6da810a0e90' User entered 'No (N)'	System	23 Sep 2020 04:43:05
	System	23 Sep 2020 04:43:05



US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-09-22T23:43:02', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '12365a1a-54a9-48e2-8bb9-f6da810a0e90' User entered '22 Sep 2020 23:43'	System	23 Sep 2020 04:43:05
	System	23 Sep 2020 04:43:05

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 21:26:48

US3342085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:06:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 21:26:48

US3342085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	23 Sep 2020 22:01:56

US3342085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '23 Sep 2020'	Ethan Shotton (b) (4)	23 Sep 2020 22:01:56

US3342085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	23 Sep 2020 22:01:56

US3342085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	Ethan Shotton (b) (4)	23 Sep 2020 22:01:56

US3342085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	23 Sep 2020 22:02:00



US3342085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'I'	System	23 Sep 2020 22:02:00

US3342085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	02 Oct 2020 15:36:38

US3342085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '2 Oct 2020'	Ethan Shotton (b) (4)	02 Oct 2020 15:36:38

US3342085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	02 Oct 2020 15:36:38

US3342085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	Ethan Shotton (b) (4)	02 Oct 2020 15:36:38

US3342085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	02 Oct 2020 15:36:42

US3342085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '1'	System	02 Oct 2020 15:36:42

US3342085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:52:29



US3342085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:52:29

US3342085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:52:29

US3342085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:52:29

US3342085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:52:32

US3342085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'I'	System	07 Oct 2020 18:52:32

US3342085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:08:27

US3342085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 11:54:09
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' answered with 'Completed' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 21:30:00
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:08:01
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 20:08:27

US3342085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:08:27



US3342085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'VISIT3'	System	16 Oct 2020 20:08:27

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '14:35'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '16 Oct 2020 14:35'	System	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	16 Oct 2020 20:09:19
User entered '98.0' F reason for change: Data Entry Error	System	16 Oct 2020 20:09:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 20:09:11
User entered '98.0' (non-conformant).	System	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:11



US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '106'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'bpm'	System	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '14'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'breaths/min'	System	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '135'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '87'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:11

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered 'mmHg'	System	16 Oct 2020 20:09:11



US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48

US3342085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48

US3342085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:25

US3342085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:25

US3342085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:29:46

US3342085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:29:46

US3342085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered '14:58'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:29:46

US3342085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '16 Oct 2020 14:58'	System	04 Nov 2020 21:29:46



US3342085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:33:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 20:09:29

US3342085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:46:48
User entered '1'	System	16 Oct 2020 20:09:29

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 64'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-10-19T07:44:37', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '87e08daf-46d7-448c-abef-d6679f0b28a6'	System	19 Oct 2020 12:44:58
User entered 'No (N)'	System	19 Oct 2020 12:44:58

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-10-19T07:44:50', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '87e08daf-46d7-448c-abef-d6679f0b28a6'	System	19 Oct 2020 12:44:58
User entered 'No (N)'	System	19 Oct 2020 12:44:58

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-10-19T07:44:54', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '87e08daf-46d7-448c-abef-d6679f0b28a6' User entered '19 Oct 2020 07:44:54'	System	19 Oct 2020 12:44:58
	System	19 Oct 2020 12:44:58

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 20:01:54



US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 71'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-10-27T18:07:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'b33ce058-e5c8-4139-8284-a045b79e3b24'	System	27 Oct 2020 23:07:56
User entered 'No (N)'	System	27 Oct 2020 23:07:56

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-10-27T18:07:47', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'b33ce058-e5c8-4139-8284-a045b79e3b24'	System	27 Oct 2020 23:07:56
User entered 'No (N)'	System	27 Oct 2020 23:07:56

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-10-27T18:07:50', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'b33ce058-e5c8-4139-8284-a045b79e3b24' User entered '27 Oct 2020 18:07:50'	System	27 Oct 2020 23:07:56
	System	27 Oct 2020 23:07:56

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 78'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-10-31T00:01:45', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '61132c29-2239-41b7-9238-09bcd8609a98'	System	31 Oct 2020 05:02:12
User entered 'No (N)'	System	31 Oct 2020 05:02:12



US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-10-31T00:02:06', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '61132c29-2239-41b7-9238-09bcd8609a98'	System	31 Oct 2020 05:02:12
User entered 'No (N)'	System	31 Oct 2020 05:02:12

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-10-31T00:02:09', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '61132c29-2239-41b7-9238-09bcd8609a98' User entered '31 Oct 2020 00:02:09'	System	31 Oct 2020 05:02:12
	System	31 Oct 2020 05:02:12

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered 'Day 92'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:02', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered 'Yes (Y)'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079'	System	15 Nov 2020 22:09:25
User entered 'No (N)'	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:18', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered 'Yes (Y)'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25



US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '0'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '1'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '1'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '1'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '0'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '1'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '0'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '0'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25



US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '1'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '0'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '0'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '1'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '1'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '1'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '0'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '0'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25



US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '0'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:08:48', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079'	System	15 Nov 2020 22:09:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:09:05', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079'	System	15 Nov 2020 22:09:25
User entered 'Yes (Y)'	System	15 Nov 2020 22:09:25

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:09:10', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079'	System	15 Nov 2020 22:09:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 22:09:25

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-11-15T16:09:14', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0851e224-a439-4d93-9385-f825e8f50079' User entered '15 Nov 2020 16:09:14'	System	15 Nov 2020 22:09:25
	System	15 Nov 2020 22:09:25

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.	System	17 Aug 2020 20:01:54
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 20:01:54

US3342085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:42:25
Data entry locked.		
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 20:01:54
	System	17 Aug 2020 20:01:54

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:38:04



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:38:04

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-12-02T09:07:22', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'fcfd6363-3da0-4bec-9a1d-9e26abaadeb8'	System	02 Dec 2020 15:07:46
User entered 'No (N)'	System	02 Dec 2020 15:07:46

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-12-02T09:07:37', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'fcfd6363-3da0-4bec-9a1d-9e26abaadeb8'	System	02 Dec 2020 15:07:46
User entered 'No (N)'	System	02 Dec 2020 15:07:46



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-12-02T09:07:43', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'fcfd6363-3da0-4bec-9a1d-9e26abaadeb8' User entered '02 Dec 2020 09:07:43'	System	02 Dec 2020 15:07:46
	System	02 Dec 2020 15:07:46

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-12-16T15:04:22', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4e3e043a-cd23-4179-ae96-bdcffd8f47f2'	System	16 Dec 2020 21:04:29
User entered 'No (N)'	System	16 Dec 2020 21:04:29



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-12-16T15:04:25', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4e3e043a-cd23-4179-ae96-bdcffd8f47f2'	System	16 Dec 2020 21:04:29
User entered 'No (N)'	System	16 Dec 2020 21:04:29

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-12-16T15:04:27', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4e3e043a-cd23-4179-ae96-bdcffd8f47f2' User entered '16 Dec 2020 15:04:27'	System	16 Dec 2020 21:04:29
	System	16 Dec 2020 21:04:29

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:38:04

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-12-25T12:25:24', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6ce5446c-ddf7-479d-a88f-7bb149a8feda' User entered 'No (N)'	System	25 Dec 2020 18:25:34
	System	25 Dec 2020 18:25:34

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-12-25T12:25:28', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6ce5446c-ddf7-479d-a88f-7bb149a8feda' User entered 'No (N)'	System	25 Dec 2020 18:25:34
	System	25 Dec 2020 18:25:34

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2020-12-25T12:25:31', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '6ce5446c-ddf7-479d-a88f-7bb149a8feda' User entered '25 Dec 2020 12:25:31'	System	25 Dec 2020 18:25:34
	System	25 Dec 2020 18:25:34



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-02T18:33:38', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a2d1d6ef-ba3d-4a7f-a4a7-2cb4c6ee2f46'	System	03 Jan 2021 00:34:00
User entered 'No (N)'	System	03 Jan 2021 00:34:00

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-02T18:33:55', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a2d1d6ef-ba3d-4a7f-a4a7-2cb4c6ee2f46'	System	03 Jan 2021 00:34:00
User entered 'No (N)'	System	03 Jan 2021 00:34:00

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-02T18:33:58', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a2d1d6ef-ba3d-4a7f-a4a7-2cb4c6ee2f46'	System	03 Jan 2021 00:34:00
User entered '02 Jan 2021 18:33:58'	System	03 Jan 2021 00:34:00

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:38:04

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-08T23:15:56', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3ac39b36-ba61-4fe6-974a-a9c309e0d470'	System	09 Jan 2021 05:16:07
User entered 'No (N)'	System	09 Jan 2021 05:16:07

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-08T23:16:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3ac39b36-ba61-4fe6-974a-a9c309e0d470'	System	09 Jan 2021 05:16:07
User entered 'No (N)'	System	09 Jan 2021 05:16:07

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-08T23:16:03', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '3ac39b36-ba61-4fe6-974a-a9c309e0d470' User entered '08 Jan 2021 23:16:03'	System	09 Jan 2021 05:16:07
	System	09 Jan 2021 05:16:07

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-14T12:54:57', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f6b06021-c31b-4d35-9631-0d297a94cc88' User entered 'No (N)'	System	14 Jan 2021 18:55:07



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-14T12:55:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f6b06021-c31b-4d35-9631-0d297a94cc88'	System	14 Jan 2021 18:55:07
User entered 'No (N)'	System	14 Jan 2021 18:55:07

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-14T12:55:02', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f6b06021-c31b-4d35-9631-0d297a94cc88' User entered '14 Jan 2021 12:55:02'	System	14 Jan 2021 18:55:07

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-22T18:12:29', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4a3262c1-813b-4231-907c-1a424f9f8951'	System	23 Jan 2021 00:12:38
User entered 'No (N)'	System	23 Jan 2021 00:12:38

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-22T18:12:32', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4a3262c1-813b-4231-907c-1a424f9f8951'	System	23 Jan 2021 00:12:38
User entered 'No (N)'	System	23 Jan 2021 00:12:38

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-22T18:12:35', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '4a3262c1-813b-4231-907c-1a424f9f8951'	System	23 Jan 2021 00:12:38
User entered '22 Jan 2021 18:12:35'	System	23 Jan 2021 00:12:38



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:38:04

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-29T12:06:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9c8985b1-1b61-4589-8f93-cb24a0d4916e'	System	29 Jan 2021 18:06:18
User entered 'No (N)'	System	29 Jan 2021 18:06:18

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-29T12:06:11', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9c8985b1-1b61-4589-8f93-cb24a0d4916e'	System	29 Jan 2021 18:06:18
User entered 'No (N)'	System	29 Jan 2021 18:06:18

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-01-29T12:06:14', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9c8985b1-1b61-4589-8f93-cb24a0d4916e' User entered '29 Jan 2021 12:06:14'	System	29 Jan 2021 18:06:18
	System	29 Jan 2021 18:06:18

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

[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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-04T20:01:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0d33bf6b-be94-4d4b-8f17-f8677ff101af' User entered 'Yes (Y)'	System	05 Feb 2021 02:04:39
	System	05 Feb 2021 02:04:39

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-04T20:01:07', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0d33bf6b-be94-4d4b-8f17-f8677ff101af' User entered 'No (N)'	System	05 Feb 2021 02:04:39
	System	05 Feb 2021 02:04:39

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-04T20:01:11', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0d33bf6b-be94-4d4b-8f17-f8677ff101af' User entered 'No (N)'	System	05 Feb 2021 02:04:39

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-04T20:01:18', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0d33bf6b-be94-4d4b-8f17-f8677ff101af' User entered 'Yes (Y)'	System	05 Feb 2021 02:04:39

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Please 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-04T20:01:25', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0d33bf6b-be94-4d4b-8f17-f8677ff101af'	System	05 Feb 2021 02:04:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Feb 2021 02:04:39

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-04T20:01:28', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0d33bf6b-be94-4d4b-8f17-f8677ff101af' User entered '04 Feb 2021 20:01:28'	System	05 Feb 2021 02:04:39

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:38:04

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-10T19:45:41', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '701a94c4-76f7-4d2f-8685-191a245bbef6'	System	11 Feb 2021 01:46:00
User entered 'No (N)'	System	11 Feb 2021 01:46:00

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-10T19:45:52', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '701a94c4-76f7-4d2f-8685-191a245bbef6' User entered 'No (N)'	System	11 Feb 2021 01:46:00
	System	11 Feb 2021 01:46:00

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-10T19:45:56', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '701a94c4-76f7-4d2f-8685-191a245bbef6'	System	11 Feb 2021 01:46:00
User entered '10 Feb 2021 19:45:56'	System	11 Feb 2021 01:46:00

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:38:04



US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-18T10:07:44', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '805b5043-a926-4f49-abdf-6aae45f15d02'	System	18 Feb 2021 16:07:53
User entered 'No (N)'	System	18 Feb 2021 16:07:53

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-18T10:07:47', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '805b5043-a926-4f49-abdf-6aae45f15d02'	System	18 Feb 2021 16:07:53
User entered 'No (N)'	System	18 Feb 2021 16:07:53

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-18T10:07:50', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '805b5043-a926-4f49-abdf-6aae45f15d02'	System	18 Feb 2021 16:07:53
User entered '18 Feb 2021 10:07:50'	System	18 Feb 2021 16:07:53

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-26T20:00:31-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '323219db-88fe-4ed6-ae76-216cb8a2891b' User entered 'No (N)'	System	27 Feb 2021 02:01:46
	System	27 Feb 2021 02:01:46

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-26T20:00:35-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '323219db-88fe-4ed6-ae76-216cb8a2891b' User entered 'No (N)'	System	27 Feb 2021 02:01:46
	System	27 Feb 2021 02:01:46



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-02-26T20:00:38-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '323219db-88fe-4ed6-ae76-216cb8a2891b' User entered '27 Feb 2021 02:00:38'	System	27 Feb 2021 02:01:46
	System	27 Feb 2021 02:01:46

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:38:04

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-03T05:45:50-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f1bd5188-965c-4019-971a-925f2f41bac5'	System	03 Mar 2021 11:46:01
User entered 'No (N)'	System	03 Mar 2021 11:46:01

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-03T05:45:55-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f1bd5188-965c-4019-971a-925f2f41bac5'	System	03 Mar 2021 11:46:01
User entered 'No (N)'	System	03 Mar 2021 11:46:01

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-03T05:45:57-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'f1bd5188-965c-4019-971a-925f2f41bac5'	System	03 Mar 2021 11:46:01
User entered '03 Mar 2021 05:45:57'	System	03 Mar 2021 11:46:01

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-11T17:35:48-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '790ba899-7bf4-4db6-8593-822df1035014'	System	11 Mar 2021 23:35:56
User entered 'No (N)'	System	11 Mar 2021 23:35:56

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-11T17:35:51-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '790ba899-7bf4-4db6-8593-822df1035014'	System	11 Mar 2021 23:35:56
User entered 'No (N)'	System	11 Mar 2021 23:35:56

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-11T17:35:54-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '790ba899-7bf4-4db6-8593-822df1035014'	System	11 Mar 2021 23:35:56
User entered '11 Mar 2021 17:35:54'	System	11 Mar 2021 23:35:56

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:38:04



US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-19T15:12:54-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'dec6d69e-3665-4449-a1e7-704693abe48f'	System	19 Mar 2021 20:13:05
User entered 'No (N)'	System	19 Mar 2021 20:13:05

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-19T15:12:56-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'dec6d69e-3665-4449-a1e7-704693abe48f'	System	19 Mar 2021 20:13:05
User entered 'No (N)'	System	19 Mar 2021 20:13:05

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-19T15:12:59-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'dec6d69e-3665-4449-a1e7-704693abe48f' User entered '19 Mar 2021 15:12:59'	System	19 Mar 2021 20:13:05
	System	19 Mar 2021 20:13:05

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-26T15:26:03-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '419aaa44-5217-4553-9992-29b6cb37e693'	System	26 Mar 2021 20:26:13
User entered 'No (N)'	System	26 Mar 2021 20:26:13

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-26T15:26:06-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '419aaa44-5217-4553-9992-29b6cb37e693'	System	26 Mar 2021 20:26:13
User entered 'No (N)'	System	26 Mar 2021 20:26:13



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-26T15:26:08-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '419aaa44-5217-4553-9992-29b6cb37e693'	System	26 Mar 2021 20:26:13
User entered '26 Mar 2021 15:26:08'	System	26 Mar 2021 20:26:13

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:38:04

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-04-07T17:46:00-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c19f5a26-6d58-4f99-839c-6720437fbbff' User entered 'No (N)'	System	07 Apr 2021 22:46:09
	System	07 Apr 2021 22:46:09



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-04-07T17:46:04-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c19f5a26-6d58-4f99-839c-6720437fbbff'	System	07 Apr 2021 22:46:09
User entered 'No (N)'	System	07 Apr 2021 22:46:09

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-04-07T17:46:06-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'c19f5a26-6d58-4f99-839c-6720437fbbff'	System	07 Apr 2021 22:46:09
User entered '07 Apr 2021 17:46:06'	System	07 Apr 2021 22:46:09

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-04-14T10:49:17-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9029b227-f9ea-4a28-87d0-7f7d32783fc5'	System	14 Apr 2021 15:50:15
User entered 'No (N)'	System	14 Apr 2021 15:50:15

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-04-14T10:49:19-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9029b227-f9ea-4a28-87d0-7f7d32783fc5'	System	14 Apr 2021 15:50:15
User entered 'No (N)'	System	14 Apr 2021 15:50:15

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-04-14T10:49:21-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '9029b227-f9ea-4a28-87d0-7f7d32783fc5' User entered '14 Apr 2021 10:49:21'	System	14 Apr 2021 15:50:15
	System	14 Apr 2021 15:50:15



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:38:04

US3342085

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-04-25T18:00:52-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a392d383-876f-4116-8d8c-2dd11ec1cefa'	System	25 Apr 2021 23:02:51
User entered 'No (N)'	System	25 Apr 2021 23:02:51

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

Have you been exposed to someone with 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 (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-04-25T18:00:54-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a392d383-876f-4116-8d8c-2dd11ec1cefa'	System	25 Apr 2021 23:02:51
User entered 'No (N)'	System	25 Apr 2021 23:02:51

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-04-25T18:00:57-05:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: 'a392d383-876f-4116-8d8c-2dd11ec1cefa'	System	25 Apr 2021 23:02:51
User entered '25 Apr 2021 18:00:57'	System	25 Apr 2021 23:02:51

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:38:04



US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:38:04

**US3342085**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:38:04

US3342085

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:38:04

US3342085

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:38:04

US3342085

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:38:04

US3342085

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:38:04

US3342085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:47

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:38:04



**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:38:04

**US3342085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:06:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:38:04
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:38:04

US3342085

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:06:47**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-02T05:18:35-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0c2a512e-66b0-4a82-9b17-a6832fa6b9f4'	System	02 Mar 2021 11:18:58
User entered 'Yes (Y)'	System	02 Mar 2021 11:18:58

US3342085

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:06:47**

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-02T05:18:45-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0c2a512e-66b0-4a82-9b17-a6832fa6b9f4'	System	02 Mar 2021 11:18:58
User entered 'No (N)'	System	02 Mar 2021 11:18:58

US3342085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:06:47

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:44:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E00F8FD3-7CB5-49B1-AE7A-F3068D926D2D)', Time: '2021-03-02T05:18:48-06:00', User OID: 'PatientReportedOutcome (US3342085)', ODM File OID: '0c2a512e-66b0-4a82-9b17-a6832fa6b9f4' User entered '02 Mar 2021 05:18:48'	System	02 Mar 2021 11:18:58
	System	02 Mar 2021 11:18:58

US3342085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	10 Nov 2020 17:41:35

US3342085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '10 Nov 2020'	Morgan Schulle (b) (4)	10 Nov 2020 17:41:35

US3342085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Morgan Schulle (b) (4)	10 Nov 2020 17:41:35



US3342085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Morgan Schulle (b) (4)	10 Nov 2020 17:41:35

US3342085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	10 Nov 2020 17:41:40

**US3342085**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:05
User entered 'I'	System	10 Nov 2020 17:41:40

US3342085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:16:34

US3342085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:16:34

US3342085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:16:34

US3342085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:16:34

US3342085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:16:39



US3342085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User entered 'I'	System	16 Dec 2020 21:16:39

US3342085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	13 Jan 2021 20:14:01

US3342085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '13 Jan 2021'	Ethan Shotton (b) (4)	13 Jan 2021 20:14:01

US3342085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	13 Jan 2021 20:14:01

US3342085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Ethan Shotton (b) (4)	13 Jan 2021 20:14:01

US3342085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	13 Jan 2021 20:14:05

US3342085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User entered 'I'	System	13 Jan 2021 20:14:05

US3342085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	23 Feb 2021 18:10:07



US3342085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:17:59
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Contacted out of window due to site closure during inclement weather. NTF to be made.' (Site from System).	Morgan Schulle (b) (4) (b) (4)	23 Feb 2021 18:11:07
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Feb 2021 18:10:07
User entered '23 Feb 2021'	Morgan Schulle (b) (4) (b) (4)	23 Feb 2021 18:10:07

US3342085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:10:07

US3342085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Morgan Schulle (b) (4)	23 Feb 2021 18:10:07

US3342085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	23 Feb 2021 18:10:12

US3342085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:47:28
User entered 'I'	System	23 Feb 2021 18:10:12

US3342085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:52:44
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:57:38
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'can confirm visit out of window, PD logged' (Site from System).	Olivia Hapanowicz (b) (4) (b) (4)	30 Mar 2021 19:53:53
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Mar 2021 19:52:44
User entered '30 Mar 2021'	Olivia Hapanowicz (b) (4) (b) (4)	30 Mar 2021 19:52:44

US3342085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User entered 'Clinic (Clinic)'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	30 Mar 2021 19:52:44



**US3342085**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 19:52:44

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '30 Mar 2021'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '14:46'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

**US3342085**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 14:46'	System	30 Mar 2021 19:54:21

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '98.5' F	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'Oral (Oral)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	



US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '88'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

**US3342085**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 19:54:21

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '12'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 19:54:21

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '138'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:54:21

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '91'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:54:21



US3342085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:27
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:27
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	01 Apr 2021 12:52:02
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '30 Mar 2021'	Ethan Shotton (b) (4)	01 Apr 2021 12:52:02
	(b) (4)	

US3342085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '14:03'	Ethan Shotton (b) (4)	01 Apr 2021 12:52:02
	(b) (4)	

**US3342085**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:06:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 14:03'	System	01 Apr 2021 12:52:02

US3342085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:54:31
	(b) (4)	

**US3342085**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 19:54:31



US3342085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:17:55

US3342085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:33
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:17:55

US3342085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:17:55

US3342085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:33
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:17:55

US3342085

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:32:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 14:17:47

**US3342085**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 14:17:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:06:47

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:19
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16 Nov 2020'	Darrell O'Brien (b) (4)	16 Nov 2020 17:31:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:06:47

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:19
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '10:45'	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:31:09



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:06:47

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:19
User entered '16 Nov 2020 10:45'	System	16 Nov 2020 17:31:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:06:47

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:19
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:31:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:06:47

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:19
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:31:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Day 1 (Day 1)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16 Nov 2020'	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '97'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User entered '%'	System	16 Nov 2020 17:32:47



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '98.9' F	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Moderate (Moderate)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Moderate (Moderate)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Moderate (Moderate)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:06:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:32:47

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Day 2 (Day 2)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '17 Nov 2020'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '91'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User entered '%'	System	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '98.7' F	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Moderate (Moderate)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:06:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:05:10

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Day 3 (Day 3)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '18 Nov 2020'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '100'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User entered '%'	System	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '98.2' F	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:06:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	18 Nov 2020 21:06:07

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Day 4 (Day 4)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '19 Nov 2020'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '100'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User entered '%'	System	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '98.2' F	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:06:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	19 Nov 2020 22:00:09

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Day 5 (Day 5)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '20 Nov 2020'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '100'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User entered '%'	System	21 Nov 2020 00:05:11



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '98.2' F	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'None (None)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:06:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Mild (Mild)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:05:11

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16 Nov 2020'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:06:22

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:06:22

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:06:22

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16 Nov 2020'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:06:22

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:06:22

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:06:22

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:06:22



US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:06:22

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Stefanie Mott (b) (4)	21 Nov 2020 00:06:22

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:06:47

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:31
User entered '0'	System	21 Nov 2020 00:06:22

US3342085

Folder: Covid-19 Assessment 16 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:06:47

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:37
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Eileen Euperio (b) (4)	25 Nov 2020 15:47:02

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:06:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

**US3342085**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

**US3342085**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
	(b) (4)	
User entered '18 Nov 2020'	Eileen Euperio (b) (4)	28 Jan 2021 23:29:29
	(b) (4)	

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:06:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29



US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:06:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	17 Mar 2021 14:22:57
	(b) (4)	
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	28 Jan 2021 23:29:29
	(b) (4)	

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:06:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User closed query 'Per GCL Lab Recon: Saliva: Re-Query: Response noted, however per preclarus report, there is no record of Saliva sample with collection date of 20 NOV 2020 in PPD GCL records. Please kindly review and update the missing sample details in Preclarus PPD portal.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 06:42:58
Query 'Per GCL Lab Recon: Saliva: Re-Query: Response noted, however per preclarus report, there is no record of Saliva sample with collection date of 20 NOV 2020 in PPD GCL records. Please kindly review and update the missing sample details in Preclarus PPD portal.Thank you.' answered with 'per delivery records, sample was NOT collected this day' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	17 Mar 2021 14:23:13
User entered empty; reason for change Data Entry Error	Eileen Euperio (b) (4) (b) (4)	17 Mar 2021 14:22:57
User opened query 'Per GCL Lab Recon: Saliva: Re-Query: Response noted, however per preclarus report, there is no record of Saliva sample with collection date of 20 NOV 2020 in PPD GCL records. Please kindly review and update the missing sample details in Preclarus PPD portal.Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 10:52:25
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 10:46:26

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:06:47

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'sample was received by PPD, req number is 1F619842121' (Site from DM).	Olivia Hapanowicz (b) (4)	(b) (4) 05 Feb 2021 15:31:41
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 05:31:50
User entered '20 Nov 2020'	Eileen Euperio (b) (4)	28 Jan 2021 23:29:29

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:06:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:06:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

**US3342085**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered empty.	(b) (4) Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:06:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:06:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29



US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:06:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
	(b) (4)	
User entered empty.	Eileen Euperio (b) (4)	28 Jan 2021 23:29:29
	(b) (4)	

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:06:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:06:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

**US3342085**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:06:47**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
	(b) (4)	
User entered empty.	Eileen Euperio (b) (4)	28 Jan 2021 23:29:29
	(b) (4)	

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:06:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:06:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:06:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
	(b) (4)	
User entered empty.	Eileen Euperio (b) (4)	28 Jan 2021 23:29:29
	(b) (4)	

US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:06:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29



US3342085

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:06:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

**US3342085**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:06:47**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered empty.	(b) (4) Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:29

US3342085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 09:07:38
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated EDC' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:45
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 05:09:23
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 17:29:15

US3342085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 08:05:34
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated EDC' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	28 Jan 2021 23:29:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 05:21:42
User entered '16 Nov 2020'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 17:29:15

US3342085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:29:15

US3342085

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User entered 'SICKD1'	System	16 Nov 2020 17:29:15

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16 Nov 2020'	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32



US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '10:53'	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User entered '16 Nov 2020 10:53'	System	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32
DataPoint set to visible.	(b) (4) System	16 Nov 2020 17:29:15

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32
DataPoint set to visible.	(b) (4) System	16 Nov 2020 17:29:15

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '98.9' F	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Oral (Oral)'	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '80'	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32



US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User entered 'bpm'	System	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12'	(b) (4) Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User entered 'breaths/min'	System	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '135'	Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User entered 'mmHg'	System	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '90'	Darrell O'Brien (b) (4)	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User entered 'mmHg'	System	16 Nov 2020 17:30:32

US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11



US3342085

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11

US3342085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	16 Nov 2020 17:30:44

US3342085

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16 Nov 2020'	Darrell O'Brien (b) (4)	16 Nov 2020 17:30:44

US3342085

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:06:47**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	28 Jan 2021 23:28:33

US3342085

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:06:47

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:06:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16 Nov 2020'	(b) (4) Eileen Euperio (b) (4)	28 Jan 2021 23:28:33

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	13 Jan 2021 00:12:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Jan 2021'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:12:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4)	13 Jan 2021 00:12:38



US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 00:12:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Jan 2021'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Ethan Shotton (b) (4)	09 Mar 2021 03:19:25
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 16:55:58

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Amendment 6 or later (Amendment 6 or later)'	Ethan Shotton (b) (4)	09 Mar 2021 03:19:25
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:55:58

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Jan 2021'	Darrell O'Brien (b) (4)	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Placebo (Placebo)'	Darrell O'Brien (b) (4)	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 12:08:12
User entered 'Placebo (Placebo)'	Darrell O'Brien (b) (4)	13 Jan 2021 00:13:05
	(b) (4)	



US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 12:08:12
User entered 'Placebo (Placebo)'	Darrell O'Brien (b) (4)	13 Jan 2021 00:13:05
	(b) (4)	

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '1'	System	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:06:47

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '1'	System	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	13 Jan 2021 00:14:38
DataPoint set to visible.	System	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38



US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	13 Jan 2021 00:14:38
DataPoint set to visible.	System	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User accepted default value 'Pre-Dose (PREDOSE)'	Darrell O'Brien (b) (4) (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Jan 2021'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '14:30'	Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '12 Jan 2021 14:30'	System	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '98.6' F	Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38



US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Oral (Oral)'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '93'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'bpm'	System	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'breaths/min'	System	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '138'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'mmHg'	System	13 Jan 2021 00:14:38



US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '89'	Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'mmHg'	System	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered missing code ND - Not Done.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	13 Jan 2021 00:14:38
DataPoint set to visible.	System	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User accepted default value 'Post-Dose (POSTDOSE)'	Darrell O'Brien (b) (4) (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Jan 2021'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16:09'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '12 Jan 2021 16:09'	System	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '98.3' F	Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Oral (Oral)'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '90'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'bpm'	System	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38



US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'breaths/min'	System	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '132'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'mmHg'	System	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '88'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'mmHg'	System	13 Jan 2021 00:14:38

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:14:57

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Jan 2021'	Darrell O'Brien (b) (4)	13 Jan 2021 00:14:57

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	13 Jan 2021 00:15:15



US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Jan 2021'	Darrell O'Brien (b) (4)	13 Jan 2021 00:15:15

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Urine (URINE)'	Darrell O'Brien (b) (4)	13 Jan 2021 00:15:15

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Negative (NEGATIVE)'	Darrell O'Brien (b) (4)	13 Jan 2021 00:15:15

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Darrell O'Brien (b) (4)	13 Jan 2021 00:15:15

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:15:15

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:15:15

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered empty.	System	13 Jan 2021 00:15:15

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:32:03
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	13 Jan 2021 00:15:42



US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:32:03
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	13 Jan 2021 00:15:42

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:32:03
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	13 Jan 2021 00:15:42

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'mRNA-1273'	System	13 Jan 2021 00:15:42
DataPoint set to visible.	System	13 Jan 2021 00:13:05

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:32:03
User entered '12 Jan 2021'	Darrell O'Brien (b) (4) (b) (4)	13 Jan 2021 00:15:42

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:32:03
User entered '15:32'	Darrell O'Brien (b) (4) (b) (4)	13 Jan 2021 00:15:42

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '12 Jan 2021 15:32'	System	13 Jan 2021 00:15:42

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:32:03
User entered 'Left Arm (LEFT ARM)'	Darrell O'Brien (b) (4) (b) (4)	13 Jan 2021 00:15:42

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:32:03
User entered 'ONCE'	System	13 Jan 2021 00:15:42



US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 00:15:42

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	13 Jan 2021 20:57:10

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 12Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 12Jan2021. Please provide accession number and tracking or clarify. Thank you.' answered with 'sample was received by PPD, req number is 1F602759195' (Site from DM).	(b) (4) (b) (4), (b) (6) Olivia Hapanowicz (b) (4)	19 Feb 2021 17:41:08 05 Feb 2021 15:28:48
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Participant Decision Visit/ OL-D1 on 12Jan2021. Please provide accession number and tracking or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 18:36:09
User entered '12 Jan 2021'	Eileen Euperio (b) (4)	13 Jan 2021 20:57:10

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '15:25'	Eileen Euperio (b) (4)	13 Jan 2021 20:57:10

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '12 Jan 2021 15:25'	System	13 Jan 2021 20:57:10

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	13 Jan 2021 20:57:37

US3342085

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:06:47**

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Jan 2021'	(b) (4) Eileen Euperio (b) (4) (b) (4)	13 Jan 2021 20:57:37

US3342085

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:06:47**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '15:29'	(b) (4) Eileen Euperio (b) (4) (b) (4)	13 Jan 2021 20:57:37



US3342085

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:06:47**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '12 Jan 2021 15:29'	System	13 Jan 2021 20:57:37

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	13 Jan 2021 00:15:48

US3342085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:52:03
User entered '1'	System	13 Jan 2021 00:15:48

US3342085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 17:02:25

US3342085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '21 Jan 2021'	Ethan Shotton (b) (4)	21 Jan 2021 17:02:25

US3342085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	21 Jan 2021 17:02:25

US3342085

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 17:02:25

US3342085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 17:02:30



US3342085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User entered 'I'	System	21 Jan 2021 17:02:30

US3342085

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User entered '1'	System	21 Jan 2021 17:02:30
DataPoint set to visible.	System	21 Jan 2021 17:02:30

US3342085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Comment added 'lab at OL-D29 collected in error. unscheduled visit created & data entered for immunogenicity assessment. protocol deviation logged.'	(b) (4) Olivia Hapanowicz (b) (4)	12 Mar 2021 17:39:39
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	23 Feb 2021 18:11:18

US3342085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Kindly choose to add the Immunogenicity form under OL-D29 folder instead of unscheduled folder and update the details as appropriate. Thanks ' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Kindly choose to add the Immunogenicity form under OL-D29 folder instead of unscheduled folder and update the details as appropriate. Thanks ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:49:03
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Kindly choose to add the Immunogenicity form under OL-D29 folder instead of unscheduled folder and update the details as appropriate. Thanks ' answered with 'unable to add immunogenicity form under OL-D29 because per protocol blood draw was not needed, which is why it needs to be added as an unscheduled folder and a PD was logged.' (Site from DM).	Olivia Hapanowicz (b) (4)	16 Mar 2021 12:17:43
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Kindly choose to add the Immunogenicity form under OL-D29 folder instead of unscheduled folder and update the details as appropriate. Thanks ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 05:07:05
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query: Thanks for your response however sample details are still missing, please update sample dated 23FEB2021 in EDC as its reported in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 05:07:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query: Thanks for your response however sample details are still missing, please update sample dated 23FEB2021 in EDC as its reported in PPD central lab.' answered with 'please clarify as under "unscheduled 23Feb2021" in EDC all sample details are entered as it is reported in PPD central lab.' (Site from DM).	Olivia Hapanowicz (b) (4)	15 Mar 2021 12:18:52
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-query: Thanks for your response however sample details are still missing, please update sample dated 23FEB2021 in EDC as its reported in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 08:20:05

US3342085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC per CCGs V.5.0 page 34-35 by initiating Immunogenicity Assessment eCRF under this folder as appropriate. Else Clarify, Thank you' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	15 Mar 2021 08:20:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC per CCGs V.5.0 page 34-35 by initiating Immunogenicity Assessment eCRF under this folder as appropriate. Else Clarify, Thank you' answered with 'data has been entered' (Site from DM).	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:51:51
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23FEB2021 is recorded under Participant Decision Visit OL-D29/OL-2 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC per CCGs V.5.0 page 34-35 by initiating Immunogenicity Assessment eCRF under this folder as appropriate. Else Clarify, Thank you' (Site from DM). User entered '23 Feb 2021'	Olivia Hapanowicz (b) (4) (b) (4) Morgan Schulle (b) (4) (b) (4)	11 Mar 2021 13:25:42 08 Mar 2021 09:26:44 23 Feb 2021 18:11:18

US3342085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	23 Feb 2021 18:11:18

US3342085

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'OLD29'	System	23 Feb 2021 18:11:18

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Schulle (b) (4) (b) (4)	23 Feb 2021 18:11:57



US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '23 Feb 2021'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '11:35'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered '23 Feb 2021 11:35'	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '99.0' F	Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Oral (Oral)'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '84'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57



**US3342085**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'bpm'	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '16'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'breaths/min'	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '125'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'mmHg'	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '87'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'mmHg'	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Schulle (b) (4) (b) (4)	23 Feb 2021 18:11:57



US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 18:12:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Schulle (b) (4)	23 Feb 2021 18:12:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Feb 2021 18:11:57
	Morgan Schulle (b) (4)	23 Feb 2021 18:11:57
	(b) (4)	

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	23 Feb 2021 23:19:04
User entered '23 Feb 2021' reason for change: Data Entry Error	Morgan Schulle (b) (4)	23 Feb 2021 23:19:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	23 Feb 2021 18:12:01
User entered empty.	Morgan Schulle (b) (4)	23 Feb 2021 18:11:57
	(b) (4)	

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 23:19:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Feb 2021 23:19:04
User entered '12:44' reason for change: Data Entry Error	Morgan Schulle (b) (4)	23 Feb 2021 23:19:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 18:12:01
User entered empty.	System	23 Feb 2021 18:12:01
	Morgan Schulle (b) (4)	23 Feb 2021 18:11:57
	(b) (4)	

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered '23 Feb 2021 12:44'	System	23 Feb 2021 23:19:04
User entered empty.	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	23 Feb 2021 23:19:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Feb 2021 23:19:04
User entered '98.8' F reason for change: Data Entry Error	Morgan Schulle (b) (4)	23 Feb 2021 23:19:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	23 Feb 2021 18:12:01
User entered empty.	Morgan Schulle (b) (4)	23 Feb 2021 18:11:57
	(b) (4)	

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	23 Feb 2021 23:19:04
User entered empty.	(b) (4)	
	Morgan Schulle (b) (4)	23 Feb 2021 18:11:57
	(b) (4)	

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 23:19:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Feb 2021 23:19:04
User entered '58' reason for change: Data Entry Error	Morgan Schulle (b) (4)	23 Feb 2021 23:19:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 18:12:01
User entered empty.	System	23 Feb 2021 18:11:57
	Morgan Schulle (b) (4)	23 Feb 2021 18:11:57
	(b) (4)	



US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'bpm'	System	23 Feb 2021 23:19:04
User entered empty.	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 23:19:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Feb 2021 23:19:04
User entered '16' reason for change: Data Entry Error	Morgan Schulle (b) (4)	23 Feb 2021 23:19:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 18:12:01
User entered empty.	System	23 Feb 2021 18:11:57
	Morgan Schulle (b) (4)	
	(b) (4)	

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'breaths/min'	System	23 Feb 2021 23:19:04
User entered empty.	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 23:19:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Feb 2021 23:19:04
User entered '123' reason for change: Data Entry Error	Morgan Schulle (b) (4)	23 Feb 2021 23:19:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 18:12:01
User entered empty.	Morgan Schulle (b) (4)	23 Feb 2021 18:11:57
	(b) (4)	

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'mmHg'	System	23 Feb 2021 23:19:04
User entered empty.	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 23:19:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	23 Feb 2021 23:19:04
User entered '86' reason for change: Data Entry Error	Morgan Schulle (b) (4)	23 Feb 2021 23:19:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	23 Feb 2021 18:12:01
User entered empty.	System	23 Feb 2021 18:11:57
	Morgan Schulle (b) (4)	
	(b) (4)	

US3342085

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'mmHg'	System	23 Feb 2021 23:19:04
User entered empty.	System	23 Feb 2021 18:11:57

US3342085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:12:10



US3342085

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:12:10

US3342085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	23 Feb 2021 18:12:21

US3342085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '23 Feb 2021'	Morgan Schulle (b) (4)	23 Feb 2021 18:12:21

US3342085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Urine (URINE)'	Morgan Schulle (b) (4)	23 Feb 2021 18:12:21

US3342085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Negative (NEGATIVE)'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:12:21

US3342085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Morgan Schulle (b) (4)	23 Feb 2021 18:12:21

**US3342085**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:06:47**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Morgan Schulle (b) (4)	23 Feb 2021 18:12:21

US3342085

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:06:47

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:12:21



**US3342085**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:06:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered empty.	System	23 Feb 2021 18:12:21

US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 23:19:31

US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 23:19:31

US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Morgan Schulle (b) (4)	23 Feb 2021 23:19:31

US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'mRNA-1273'	System	23 Feb 2021 23:19:31
DataPoint set to visible.	System	21 Jan 2021 17:02:30

US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '23 Feb 2021'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 23:19:31

US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12:14'	Morgan Schulle (b) (4)	23 Feb 2021 23:19:31

US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered '23 Feb 2021 12:14'	System	23 Feb 2021 23:19:31



US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Left Arm (LEFT ARM)'	Morgan Schulle (b) (4)	23 Feb 2021 23:19:31

US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'ONCE'	System	23 Feb 2021 23:19:31

US3342085

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 23:19:31

US3342085

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	23 Feb 2021 18:12:26

US3342085

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:33
User entered 'I'	System	23 Feb 2021 18:12:26

US3342085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:56:57

US3342085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:56:57

**US3342085**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:06:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:56:57



US3342085

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'ATTEMPTED 3 PHONE CALLS'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:56:57

US3342085

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:57:02

**US3342085**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:06:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:40:45
User entered 'I'	System	09 Mar 2021 19:57:02

US3342085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:14
	(b) (4)	

US3342085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '30 Mar 2021'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:14
	(b) (4)	

US3342085

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User entered 'Clinic (Clinic)'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	30 Mar 2021 19:55:14

**US3342085**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:06:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 19:55:14

US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	



US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '30 Mar 2021'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	

US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '14:46'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	

**US3342085**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 14:46'	System	30 Mar 2021 19:55:07

US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '98.5' F	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	

US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'Oral (Oral)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	

US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	

US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '88'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	

**US3342085**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 19:55:07



US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '12'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	

**US3342085**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 19:55:07

US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '138'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	

**US3342085**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:55:07

US3342085

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '91'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:07
	(b) (4)	

**US3342085**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:06:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 19:55:07

US3342085

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:19
	(b) (4)	

US3342085

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:55:19
	(b) (4)	



US3342085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	01 Apr 2021 12:51:48
	(b) (4)	

US3342085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '30 Mar 2021'	Ethan Shotton (b) (4)	01 Apr 2021 12:51:48
	(b) (4)	

US3342085

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
	(b) (4)	
User entered '14:03'	Ethan Shotton (b) (4)	01 Apr 2021 12:51:48
	(b) (4)	

**US3342085**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:06:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 14:03'	System	01 Apr 2021 12:51:48

US3342085

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:06:47**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:16:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '23 Feb 2021'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	12 Mar 2021 17:39:55

US3342085

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:06:47**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:16:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	12 Mar 2021 17:39:55

US3342085

Folder: Unscheduled 23 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:06:47

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:16:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Olivia Hapanowicz (b) (4)	12 Mar 2021 17:39:55

US3342085

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:06:47**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:16:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'I'	Olivia Hapanowicz (b) (4)	12 Mar 2021 17:39:55



US3342085

Folder: **Unscheduled 23 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:06:47**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:16:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Olivia Hapanowicz (b) (4)	12 Mar 2021 17:39:55

US3342085

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:16:26
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	12 Mar 2021 17:40:09

US3342085

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:16:26
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 23FEB2021 is recorded under Participant Unscheduled Visit in EDC, however the same is reported under OL-D29/OL-2 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:10:45
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 23FEB2021 is recorded under Participant Unscheduled Visit in EDC, however the same is reported under OL-D29/OL-2 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' answered with 'immunogenicity sample collected in error at OL-D29. unable to put in EDC under OL-D29 folder and an unscheduled visit had to be created to add data.' (Site from DM).	Olivia Hapanowicz (b) (4)	22 Mar 2021 12:38:12
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 23FEB2021 is recorded under Participant Unscheduled Visit in EDC, however the same is reported under OL-D29/OL-2 visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:56:56
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '23 Feb 2021'	Olivia Hapanowicz (b) (4)	12 Mar 2021 17:40:09

US3342085

Folder: Unscheduled 23 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:16:26
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12:06'	Olivia Hapanowicz (b) (4)	12 Mar 2021 17:40:09

US3342085

Folder: **Unscheduled 23 Feb 2021**

Form: **Immunogenicity Assessment**

Generated On: **09 Jun 2021 17:06:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:16:26
User entered '23 Feb 2021 12:06'	System	12 Mar 2021 17:40:09

US3342085

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:06:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:24
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 22:08:13
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:32:52
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 15:54:51

**US3342085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:47**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:37:22
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'Subject tested negative for COVID-19 during scheduled illness visit. AE is now resolved.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	16 Dec 2020 21:08:17
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 15:37:58
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral upper respiratory tract infection, LLT: Viral upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 16:06:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 16:06:44
Data point term sent to Coder	System	16 Nov 2020 16:05:59
User entered 'Viral Upper Respiratory Infection'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59



US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '13 Nov 2020'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User entered empty.	System	16 Nov 2020 16:04:59

**US3342085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	16 Dec 2020 21:08:42
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '21 Nov 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	16 Dec 2020 21:28:48
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Dec 2020 21:08:56
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	16 Dec 2020 21:08:56
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	16 Dec 2020 21:08:56
User entered '19 Nov 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	16 Dec 2020 21:08:56
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	16 Dec 2020 21:08:42
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Dec 2020 21:08:42
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59



US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User entered empty.	System	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59



US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'Not Related (NOT RELATED)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'Not Related (NOT RELATED)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59



US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User closed query 'Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 14:59:31
Query 'Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify.' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	05 Feb 2021 15:29:51
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	05 Feb 2021 15:29:46
User opened query 'Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 10:55:47
User entered 'None (NONE)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'l'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	16 Dec 2020 21:08:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'SUBJECT CALLED SITE AT 08:05 (16NOV2020) AND REPORTED HAVING HA/ST/LOSS OF SMELL/COUGH STARTING 13NOV2020. PT WENT TO PCP AND RECIEVED COVID RAPID TEST (RESULT (-)). GIVEN VIRTUSSIN 5ML PO PRN SINCE 15NOV2020 BY PCP. RAPID TEST WAS ON 15NOV2020.	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 17:28:43
Also reports chills, fatigue, SOB, congestion, rhinitis, diarrhea.' reason for change: New Information		
User entered 'Subject called site at 08:05 (16NOV2020) and reported having HA/ST/Loss of smell/cough starting 13NOV2020. Pt went to PCP and recieved COVID rapid test (result (-)). Given Virtussin 5mL PO PRN since 15NOV2020 by PCP. Rapid test was on 15NOV2020.'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User entered '0'	System	16 Nov 2020 16:04:59



US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20
User entered '1'	System	16 Nov 2020 16:04:59

US3342085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:20

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:38:59
User entered	System	08 Feb 2021 12:38:55
'USA-US203-2021-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	08 Feb 2021 12:38:55

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:03:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:03:49
Data point term sent to Coder	System	05 Feb 2021 21:03:20
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:03:09
User entered 'Appendicitis' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:03:09
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 20:40:45
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '02 Feb 2021'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45



**US3342085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

**US3342085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:06:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Feb 2021 21:03:09
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	05 Feb 2021 21:03:09
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Feb 2021 21:03:09
User entered '03 Feb 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:03:09
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Feb 2021 20:40:45
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Feb 2021 20:40:45
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

**US3342085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:06:47**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

**US3342085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:06:47**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:03:09
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:03:09
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 20:40:45
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:03:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:03:09
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 20:40:45
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45



US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '1' reason for change: Data Entry Error	Ethan Shotton (b) (4)	05 Feb 2021 21:03:09
User entered '0'	(b) (4) Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '02 Feb 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4)	05 Feb 2021 21:03:09
User entered empty.	(b) (4) Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '03 Feb 2021' reason for change: Data Entry Error	Ethan Shotton (b) (4)	05 Feb 2021 21:03:09
User entered empty.	(b) (4) Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:03:09
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45



US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '0'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:03:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:03:09
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 20:40:45
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:03:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:03:09
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 20:40:45
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'None (NONE)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	18 Mar 2021 21:07:35
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	08 Mar 2021 23:06:12
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:03:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:03:09
User entered 'None (NONE)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:03:09
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 20:40:45
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Feb 2021 21:03:09
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Feb 2021 20:40:45
User entered '0'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '1' reason for change: Data Entry Error	Ethan Shotton (b) (4)	05 Feb 2021 21:03:09
User entered '0'	(b) (4) Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered '1' reason for change: Data Entry Error	Ethan Shotton (b) (4)	05 Feb 2021 21:03:09
User entered '0'	(b) (4) Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45



US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 17:54:10
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 20:40:45

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:45:27
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 15:45:24
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 15:45:18
User entered 'SUBJECT REPORTED BEING ADMITTED TO THE HOSPITAL FOR ABDOMINAL PAIN ON 02FEB2021 AND HAVING AN APPENDECTOMY FOR APPENDICITIS ON 03FEB2021. SUBJECT WAS DISCHARGED FROM THE HOSPITAL POST-SURGERY ON 03FEB2021.	Olivia Hapanowicz (b) (4) (b) (4)	30 Mar 2021 19:44:39
PATIENT FILLED OUT MEDICAL RELEASE FORM 30MAR2021. PATIENT'S COVID-19 TEST FROM HOSPITAL WAS NEGATIVE. PATIENT ALSO REPORTED THAT THERE WAS NO UNDERLYING CONDITION/RISK FACTORS THAT CAUSED THE APPENDICITIS. PATIENT WAS UNSURE ABOUT LAB WORK DONE AT HOSPITAL. PATIENT DID HAVE CT SCAN ON 02FEB2021 (REPORTED ON CONPROCEDURES), WHICH CONFIRMED APPENDICITIS DIAGNOSIS. AWAITING MEDICAL RECORDS FOR FURTHER INFORMATION.' reason for change: Data Entry Error		

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Patient had CT scan to confirm appendicitis diagnosis. Patient did not report any other lab work. ' (Site from Safety).	Olivia Hapanowicz (b) (4)	(b) (4) 30 Mar 2021 19:44:12
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Pt reported that there was no underlying condition/pre-disposing risk factors associated with this event.' (Site from Safety).	Olivia Hapanowicz (b) (4)	(b) (4) 30 Mar 2021 19:43:37
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Patient's COVID-19 test was negative. ' (Site from Safety).	Olivia Hapanowicz (b) (4)	(b) (4) 30 Mar 2021 19:12:13
User entered 'SUBJECT REPORTED BEING ADMITTED TO THE HOSPITAL FOR ABDOMINAL PAIN ON 02FEB2021 AND HAVING AN APPENDECTOMY FOR APPENDICITIS ON 03FEB2021. SUBJECT WAS DISCHARGED FROM THE HOSPITAL POST-SURGERY ON 03FEB2021	Olivia Hapanowicz (b) (4)	(b) (4) 30 Mar 2021 19:11:22
Patient filled out medical release form 30Mar2021. Patient's COVID-19 test from hospital was NEGATIVE. Patient also reported that there was NO underlying condition/risk factors that caused the appendicitis. Patient was unsure about lab work done at hospital. Patient did have CT scan on 02Feb2021 (reported on conprocedures), which confirmed appendicitis diagnosis. Awaiting medical records for further information.' reason for change: Data Entry Error		
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 17:54:28

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2115 of 2362

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:54:10
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:28:13
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:28:05
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:27:59
User entered 'Subject reported being admitted to the hospital for abdominal pain on 02Feb2021 and having an appendectomy for appendicitis on 03Feb2021. Subject was discharged from the hospital post-surgery on 03Feb2021' reason for change: Data Entry Error	Ethan Shotton (b) (4)	05 Feb 2021 21:03:09
User entered empty.	Ethan Shotton (b) (4)	05 Feb 2021 20:40:45

**US3342085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:03:09

US3342085

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 20:40:45

**US3342085**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 21:03:09



US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:06:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:24
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:54:51
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:10:49

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 21:13:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 21:13:23
Data point term sent to Coder	System	17 Aug 2020 21:11:47
User entered 'Adderall'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Attention deficit disorder'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
	(b) (4)	
Signature has been broken.	Ethan Shotton (b) (4)	18 Mar 2021 21:03:54
	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered '20'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'mg (mg)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Oral (ORAL)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:43:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 21:11:45
User entered 'un UNK 2011'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4)	
	Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:11:45



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:11:45

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:11:45

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 21:11:45

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 21:15:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:15:11
Data point term sent to Coder	System	17 Aug 2020 21:14:51
User entered 'Citalopram hydrobromide'	Tiffany Lemuz (b) (4) (b) (4) (b) (4)	17 Aug 2020 21:14:22

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'Depression'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '40'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'mg (mg)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Oral (ORAL)'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:43:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 21:14:22
User entered 'un UNK 2010'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22



US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:14:22

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:14:22

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:14:22

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 21:14:22

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 21:17:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 21:17:17
Data point term sent to Coder	System	17 Aug 2020 21:15:55
User entered 'Levothyroxine sodium'	Tiffany Lemuz (b) (4) (b) (4)	17 Aug 2020 21:15:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'Hypothyroidism'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered '100'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:08:45
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated to microgram.' (Site from DM).	Andrew Bell (b) (4) (b) (4)	13 Oct 2020 16:39:07
User entered 'ug (ug)' reason for change: Data Entry Error	Andrew Bell (b) (4) (b) (4)	13 Oct 2020 16:38:54
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:41:10
User entered 'mg (mg)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'once daily (QD)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'Oral (ORAL)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 13:43:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 21:15:17
User entered 'un UNK 2015'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered '0'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered empty.	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
	(b) (4)	
User entered 'No (N)'	Tiffany Lemuz (b) (4)	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:15:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 21:15:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 17:59:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 17:59:38
Data point term sent to Coder	System	10 Nov 2020 17:43:27
User entered 'INFLUENZA VACCINE'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15



US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'INFLUENZA PROPHYLAXIS'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:47**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0.5'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'mL (mL)'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'once (ONCE)'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Intramuscular (INTRAMUSCULAR)'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Oct 2020'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:06:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '12 Oct 2020'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Morgan Schulle (b) (4)	10 Nov 2020 17:43:15

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User entered empty.	System	10 Nov 2020 17:43:15

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User entered empty.	System	10 Nov 2020 17:43:15



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:41
User entered empty.	System	10 Nov 2020 17:43:15

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: CODEINE PHOSPHATE;GUAIFENESIN, PRODUCTSYNONYM: VIRTUSSIN AC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:44:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 07:44:54
Data point term sent to Coder	System	16 Nov 2020 16:07:00
User entered 'Virtussin'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Viral URI (AE)'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '5'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'mL (mL)'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'as needed (PRN)'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17



US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Oral (ORAL)'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '15 Nov 2020'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	16 Dec 2020 21:29:31
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '19 Nov 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4)	16 Dec 2020 21:29:31
User entered empty.	Darrell O'Brien (b) (4)	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:06:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Per CDM: Was medication taken for solicited event is "Yes". However, indication is "VIRAL URI (AE)". Please confirm and update if necessary. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:22:26
Query 'Per CDM: Was medication taken for solicited event is "Yes". However, indication is "VIRAL URI (AE)". Please confirm and update if necessary. Thank you' answered with 'not for solicited AR, for an AE' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	25 Nov 2020 15:46:37
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	25 Nov 2020 15:46:22
User opened query 'Per CDM: Was medication taken for solicited event is "Yes". However, indication is "VIRAL URI (AE)". Please confirm and update if necessary. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:00:52
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	16 Nov 2020 16:06:17



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User entered empty.	System	16 Nov 2020 16:06:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User entered empty.	System	16 Nov 2020 16:06:17

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:47
User entered empty.	System	16 Nov 2020 16:06:17

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Feb 2021 09:59:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:59:52
Data point term sent to Coder	System	05 Feb 2021 21:38:56
User entered 'Ketoralac'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:38:53

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:26
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:24
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Appendicitis AE'	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:21
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication, and it appears to exceed the maximum recommended daily dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:17:03
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication, and it appears to exceed the maximum recommended daily dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Dose has been reviewed and corrected.' (Site from DM).	Morgan Schulle (b) (4) (b) (4)	23 Feb 2021 18:22:40
User entered '10' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	23 Feb 2021 18:22:11
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication, and it appears to exceed the maximum recommended daily dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	20 Feb 2021 14:01:32
User entered '50'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:38:53

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'mg (mg)'	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:17
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:13
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'four times daily (QID)' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	23 Feb 2021 18:22:11
User entered 'three times daily (TID)' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	23 Feb 2021 18:18:42
User entered 'other (OTHER)'	(b) (4)	
	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53
	(b) (4)	

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:11
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Per CDM: Please clarify if "Q.6.H" means after every 6 hours. If yes, then please consider Please consider selecting "Four times daily" instead of selecting Other and writing "Every 6 hours". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:17:17
Query 'Per CDM: Please clarify if "Q.6.H" means after every 6 hours. If yes, then please consider Please consider selecting "Four times daily" instead of selecting Other and writing "Every 6 hours". Thank you!' answered with 'Change has been made' (Site from DM).	Morgan Schulle (b) (4) (b) (4)	23 Feb 2021 18:22:47
User entered empty; reason for change Data Entry Error	Morgan Schulle (b) (4) (b) (4)	23 Feb 2021 18:18:42
User opened query 'Per CDM: Please clarify if "Q.6.H" means after every 6 hours. If yes, then please consider Please consider selecting "Four times daily" instead of selecting Other and writing "Every 6 hours". Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:00:11
User entered 'q.6.h.'	Ethan Shotton (b) (4) (b) (4)	05 Feb 2021 21:38:53

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:08
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:06
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '03 Feb 2021'	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:01
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:33:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 18:18:42
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53
	(b) (4)	



US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:32:57
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '07 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	23 Feb 2021 18:20:07
User entered '10 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Morgan Schulle (b) (4)	23 Feb 2021 18:18:42
User entered empty.	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53
	(b) (4)	

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:06:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:32:56
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	Ethan Shotton (b) (4)	05 Feb 2021 21:38:53

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
User entered '4'	System	23 Feb 2021 18:22:11
User entered '3'	System	23 Feb 2021 18:18:42
User entered empty.	System	05 Feb 2021 21:38:53

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
User entered '1'	System	23 Feb 2021 18:18:42
User entered empty.	System	05 Feb 2021 21:38:53

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:01:53
User entered '804 (804)'	System	23 Feb 2021 18:18:42
User entered empty.	System	05 Feb 2021 21:38:53

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:47

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:06:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:06:33
Data point term sent to Coder Coding entries removed.	System Olivia Hapanowicz (b) (4) (b) (4)	22 Mar 2021 19:18:13 22 Mar 2021 19:17:46
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:51:51
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 12:05:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 12:05:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 20:17:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 20:17:45
Data point term sent to Coder User entered 'Botox'	System (b) (4), (b) (6) (b) (4)	03 Mar 2021 20:16:41 03 Mar 2021 20:15:52

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2229 of 2362

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:47

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:56:39
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'CORRESPONDS TO NEW EDIARY PROMPT ABOUT COSMETIC INJECTIONS & DERMAL FILLERS. NO CORRESPONDING AE OR MH TO BE ADDED.' (Site from DM).	Olivia Hapanowicz (b) (4)	30 Mar 2021 12:16:32
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:38:41
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User closed query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:38:39
Query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' answered with 'not a procedure, indication updated' (Site from DM).	Olivia Hapanowicz (b) (4)	22 Mar 2021 19:18:07
Signature has been broken.	Olivia Hapanowicz (b) (4)	22 Mar 2021 19:17:46
User entered 'ELECTIVE (COSMETIC)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	22 Mar 2021 19:17:46



US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:36:25
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Elective Cosmetic Procedure'	(b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '1'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Injection'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:15:52

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:15:52



US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:47

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A HAEMAGGLUTININ COMPLEX, PRODUCTSYNONYM: DYSPORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:18:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 13:18:13
Data point term sent to Coder Coding entries removed.	System Olivia Hapanowicz (b) (4) (b) (4)	22 Mar 2021 19:20:15 22 Mar 2021 19:19:33
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:51:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A HAEMAGGLUTININ COMPLEX, PRODUCTSYNONYM: DYSPORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 12:56:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 12:56:58
Data point term sent to Coder User entered 'Dysport'	System (b) (4), (b) (6) (b) (4)	03 Mar 2021 20:21:48 03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:47

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:56:51
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'CORRESPONDS TO NEW EDIARY PROMPT ABOUT COSMETIC INJECTIONS & DERMAL FILLERS. NO CORRESPONDING AE OR MH TO BE ADDED.' (Site from DM).	Olivia Hapanowicz (b) (4)	30 Mar 2021 12:17:09
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:38:53
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User closed query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:40:53
Query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' answered with 'not a procedure, indication updated' (Site from DM).	Olivia Hapanowicz (b) (4)	22 Mar 2021 19:20:03
Signature has been broken.	Olivia Hapanowicz (b) (4)	22 Mar 2021 19:19:33
User entered 'ELECTIVE (cosmetic)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	22 Mar 2021 19:19:33

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:36:37
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Elective Cosmetic Procedure'	(b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '1'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Injection'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:21:18



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:21:18

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:21:18

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:47

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: JUVEDERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:12:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:12:39
Data point term sent to Coder Coding entries removed.	System Olivia Hapanowicz (b) (4) (b) (4)	22 Mar 2021 19:21:15 22 Mar 2021 19:20:51
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:51:51
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: JUVEDERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 20:24:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 20:24:45
Data point term sent to Coder User entered 'Juvederm'	System (b) (4), (b) (6) (b) (4)	03 Mar 2021 20:23:53 03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:47

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:57:18
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'CORRESPONDS TO NEW EDIARY PROMPT ABOUT COSMETIC INJECTIONS & DERMAL FILLERS. NO CORRESPONDING AE OR MH TO BE ADDED.' (Site from DM).	Olivia Hapanowicz (b) (4)	30 Mar 2021 12:18:23
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:39:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User closed query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:41:14
Query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' answered with 'not a procedure, indication updated' (Site from DM).	Olivia Hapanowicz (b) (4)	22 Mar 2021 19:21:15
Signature has been broken.	Olivia Hapanowicz (b) (4)	22 Mar 2021 19:20:51
User entered 'ELECTIVE (COSMETIC)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	22 Mar 2021 19:20:51

US3342085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:36:47
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 20:23:39
User entered 'Elective Cosmetic Procedure' reason for change: Data Entry Error	System	03 Mar 2021 20:23:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Mar 2021 20:23:30
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '1'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Injection'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30



US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:23:30

US3342085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:06:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:23:30

US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:06:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:46:24
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:10
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	05 Feb 2021 21:38:59

US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:24
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '03 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Ethan Shotton (b) (4)	05 Feb 2021 21:39:36
User entered '05 Feb 2021'	(b) (4)	
	Ethan Shotton (b) (4)	05 Feb 2021 21:39:26
	(b) (4)	



US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:24
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Appendectomy'	Ethan Shotton (b) (4)	05 Feb 2021 21:39:26

US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:24
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'Adverse Event (AE)'	Ethan Shotton (b) (4)	05 Feb 2021 21:39:26

US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:06:47

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 17:55:24
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered empty.	Ethan Shotton (b) (4)	05 Feb 2021 21:39:26

US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User entered '02 Feb 2021'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:45:25

US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User entered 'CT scan'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:45:25

US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User entered 'Diagnostic (DIAGNOSTIC)'	Olivia Hapanowicz (b) (4)	30 Mar 2021 19:45:25

US3342085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:06:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:22:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User entered empty.	(b) (4) Olivia Hapanowicz (b) (4)	30 Mar 2021 19:45:25

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'USA-US203-2021-MRNA-1273-P301000007'	System	08 Feb 2021 12:38:55



US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Paul'	System	08 Feb 2021 12:38:55



US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Pickrell'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:18:11
User entered 'US'	System	08 Feb 2021 12:39:21

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	31 Mar 2021 15:46:44
User entered '3'	System	19 Mar 2021 13:55:38
User entered '2'	System	09 Mar 2021 14:18:25
User entered '1'	System	08 Feb 2021 12:39:21

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'USA-US203-2021-MRNA-1273-P301000007'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55



US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Paul'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Pickrell'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:18:11
User entered 'US'	System	08 Feb 2021 12:39:21

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	31 Mar 2021 15:46:44
User entered '3'	System	19 Mar 2021 13:55:38
User entered '2'	System	09 Mar 2021 14:18:25
User entered '1'	System	08 Feb 2021 12:39:21

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:06:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '08/Feb/2021 12:39'	(b) (4) System	08 Feb 2021 12:39:21



US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:06:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:18:11
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 12:39:21

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'USA-US203-2021-MRNA-1273-P301000007'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55



US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Paul'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Pickrell'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:18:11
User entered 'US'	System	08 Feb 2021 12:39:21

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	31 Mar 2021 15:46:44
User entered '3'	System	19 Mar 2021 13:55:38
User entered '2'	System	09 Mar 2021 14:18:25
User entered '1'	System	08 Feb 2021 12:39:21

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:06:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered '09/Mar/2021 08:18'	(b) (4) System	09 Mar 2021 14:18:25

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:06:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 13:54:40
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:18:25

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'USA-US203-2021-MRNA-1273-P301000007'	System	08 Feb 2021 12:38:55



**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Paul'	System	08 Feb 2021 12:38:55



US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Pickrell'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:18:11
User entered 'US'	System	08 Feb 2021 12:39:21

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	31 Mar 2021 15:46:44
User entered '3'	System	19 Mar 2021 13:55:38
User entered '2'	System	09 Mar 2021 14:18:25
User entered '1'	System	08 Feb 2021 12:39:21

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:06:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered '19/Mar/2021 09:55'	(b) (4) System	19 Mar 2021 13:55:38

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:06:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 15:46:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:03:52
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 13:55:38

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'USA-US203-2021-MRNA-1273-P301000007'	System	08 Feb 2021 12:38:55

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55



US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Yes (Y)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'No (N)'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Paul'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:39:13
User entered 'Pickrell'	System	08 Feb 2021 12:38:55

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:51:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:18:11
User entered 'US'	System	08 Feb 2021 12:39:21



**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:06:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	31 Mar 2021 15:46:44
User entered '3'	System	19 Mar 2021 13:55:38
User entered '2'	System	09 Mar 2021 14:18:25
User entered '1'	System	08 Feb 2021 12:39:21

**US3342085**

**Folder: SAE USA-US203-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:06:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User entered '31/Mar/2021 10:46'	(b) (4) System	31 Mar 2021 15:46:44

US3342085

Folder: SAE USA-US203-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:06:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:29:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:46:44