

US3542043 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:47:42

All time stamps listed in this document are displayed in GMT

US3542043

Form: Participant Creation

Data signed: (b) (4) 27 Aug 2020 15:39:41

Generated On: 11 Aug 2021 22:47:42

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[Participant ID](#)

US3542043

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

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US3542043

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 27 Aug 2020 15:39:51

Generated On: 11 Aug 2021 22:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 27 Aug 2020 15:39:41

Generated On: 11 Aug 2021 22:47:42

Date of Birth (MMM yyyy)	(b) (6) 1993
Age	26
Age Units	YEARS
Age (Derived)	26
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	True
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 27 Aug 2020 15:39:41

Generated On: 11 Aug 2021 22:47:42

Date of Informed Consent ( <i>dd MMM yyyy</i> )	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 27 Aug 2020 15:39:41

Generated On: 11 Aug 2021 22:47:42

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 27 Aug 2020 15:39:51

Generated On: 11 Aug 2021 22:47:42

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 27 Aug 2020 15:39:41

Generated On: 11 Aug 2021 22:47:42

Condition	MIGRAINES
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)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 27 Aug 2020 15:39:41

Generated On: 11 Aug 2021 22:47:42

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 27 Aug 2020 15:39:41

Generated On: 11 Aug 2021 22:47:42

Condition	SYSTOLIC MURMUR
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 27 Aug 2020 15:39:51

Generated On: 11 Aug 2021 22:47:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 08:52
Height (xxx.x)	167 cm
Weight (xxx.x)	159 lb
BMI (xxx.x)	25.91442 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Nov 2020 21:46:19

Generated On: 11 Aug 2021 22:47:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 27 Aug 2020 15:39:41

Generated On: 11 Aug 2021 22:47:42

Date of assessment (dd MMM yyyy) 24 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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 27 Aug 2020 15:39:51

Generated On: 11 Aug 2021 22:47:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	24 AUG 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)	

US3542043

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 27 Aug 2020 15:39:51

Generated On: 11 Aug 2021 22:47:42

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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** ECONOMIST

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 27 Aug 2020 15:39:51

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 27 Aug 2020 15:39:52

Generated On: 11 Aug 2021 22:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Sep 2020 04:16:21

Generated On: 11 Aug 2021 22:47:42

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 107170

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☒   
 >=18 and <65 years and at risk ☐   
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 27 Aug 2020 15:39:52

Generated On: 11 Aug 2021 22:47:42

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 27 Aug 2020 15:39:52

Generated On: 11 Aug 2021 22:47:42

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)	24 AUG 2020
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 08:52
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 27 Aug 2020 15:39:52

Generated On: 11 Aug 2021 22:47:42

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)	24 AUG 2020
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 10:37
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)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Nov 2020 21:46:19

Generated On: 11 Aug 2021 22:47:42

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 17 Sep 2020 04:16:59

Generated On: 11 Aug 2021 22:47:42

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 27 Aug 2020 15:39:52

Generated On: 11 Aug 2021 22:47:42

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 10:06 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 10:06

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 27 Aug 2020 15:39:52

Generated On: 11 Aug 2021 22:47:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 AUG 2020

Collection time (00:00-23:59)

09:18 (24 HR)

Collection date and time (derived)

24 AUG 2020 09:18

US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 27 Aug 2020 15:39:51

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:24	24 AUG 2020 09:24
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 27 Aug 2020 15:39:52

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 10:39

PC Open Date & Time

24 AUG 2020 10:26

PC Close Date & Time

24 AUG 2020 12:56

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**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

98.7 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	24 AUG 2020 20:31
PC Open Date & Time	24 AUG 2020 13:51
PC Close Date & Time	25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 21:03

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 01:13

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 21:10

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**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

30 AUG 2020 21:06

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

**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

24 AUG 2020 10:40

PC Open Date & Time

24 AUG 2020 10:26

PC Close Date & Time

24 AUG 2020 12:56

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**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

24 AUG 2020 20:32

PC Open Date & Time

24 AUG 2020 13:51

PC Close Date & Time

25 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 2
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input type="radio"/>
Please select one response below	
Does not interfere with activity	<input checked="" type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	25 AUG 2020 21:02
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**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

26 AUG 2020 21:06

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 4
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	27 AUG 2020 23:15
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59



US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 6
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
	Does not interfere with activity <input type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
	Does not interfere with activity <input type="radio"/>
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/>
	Any use of prescription pain reliever or prevents daily activity <input type="radio"/>
PC Time Stamp	29 AUG 2020 21:12
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 7
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	30 AUG 2020 21:06
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

**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 ☐

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 10:41
PC Open Date & Time	24 AUG 2020 10:26
PC Close Date & Time	24 AUG 2020 12:56

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**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 ☐

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 20:32
PC Open Date & Time	24 AUG 2020 13:51
PC Close Date & Time	25 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 21:02
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 21:06
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 23:16
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:42

Yes ☐

PC Time stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2288

EAB) (1725)



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:12
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

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

57 of 2288

EAB) (1725)

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 21:06
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:47:42

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

---

PC Time Stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

---

US3542043

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:47:42

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

---

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

---

US3542043

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59



US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3542043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Sep 2020 15:29:17

Generated On: 11 Aug 2021 22:47:42

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*

US3542043

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Sep 2020 15:29:17

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Sep 2020 15:16:09

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542043

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Sep 2020 04:16:59

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Sep 2020 04:16:59

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542043

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Sep 2020 04:16:59

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 02:53:49

Generated On: 11 Aug 2021 22:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Oct 2020 02:53:49

Generated On: 11 Aug 2021 22:47:42

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)	05 OCT 2020
Time of assessment (00:00-23:59)	12:02 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 12:02
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)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Oct 2020 02:53:49

Generated On: 11 Aug 2021 22:47:42

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 02:53:49

Generated On: 11 Aug 2021 22:47:42

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.*

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 08 Oct 2020 02:53:49

Generated On: 11 Aug 2021 22:47:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	5 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Oct 2020 02:53:49

Generated On: 11 Aug 2021 22:47:42

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

Which arm was used to give treatment? Left Arm ☐  
Right Arm ☐

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3542043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 02:53:49

Generated On: 11 Aug 2021 22:47:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	12:14 (24 HR)
Collection date and time (derived)	5 OCT 2020 12:14

US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Oct 2020 02:53:49

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3542043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 02:53:49

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3542043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542043

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 11 Nov 2020 18:15:33

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542043

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Oct 2020 03:22:24

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Oct 2020 03:22:24

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542043

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Oct 2020 03:22:24

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Nov 2020 21:46:19

Generated On: 11 Aug 2021 22:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Nov 2020 21:46:19

Generated On: 11 Aug 2021 22:47:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 NOV 2020
Time of assessment (00:00-23:59)	09:07 (24 HR)
Vital Signs Date and Time (derived)	02 NOV 2020 09:07
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	45 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3542043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Nov 2020 21:46:19

Generated On: 11 Aug 2021 22:47:42

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.*

US3542043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Nov 2020 04:10:14

Generated On: 11 Aug 2021 22:47:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 NOV 2020

Collection time (00:00-23:59)

09:24 (24 HR)

Collection date and time (derived)

2 NOV 2020 09:24

US3542043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Nov 2020 21:46:19

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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

02 NOV 2020 09:31:34

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 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	09 NOV 2020 10:35:49
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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	10 DEC 2020 08:11:26
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 23:26:25

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

<b>TIMEPOINT</b>	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 09:28:28
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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

14 JAN 2021 09:21:39

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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

21 JAN 2021 14:37:59

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 20:17:49

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 11:20:51

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 13:38:07
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

<b>TIMEPOINT</b>	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	06 MAR 2021 22:36:18
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

<b>TIMEPOINT</b>	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	14 MAR 2021 13:13:40
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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

20 MAR 2021 11:38:46

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 22:37:59

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 09:29:59
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

14 JUL 2021 00:01

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18 JUL 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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="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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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21 JUL 2021 00:01

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25 JUL 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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28 JUL 2021 00:01

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01 AUG 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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="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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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04 AUG 2021 00:01

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08 AUG 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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11 AUG 2021 00:01

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15 AUG 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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="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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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25 AUG 2021 00:01

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29 AUG 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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05 SEP 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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12 SEP 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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19 SEP 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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26 SEP 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

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19 DEC 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

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26 DEC 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

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02 JAN 2022 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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05 JAN 2022 00:01

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09 JAN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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 ☐

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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12 JAN 2022 00:01

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16 JAN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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 ☐

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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19 JAN 2022 00:01

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23 JAN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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 ☐

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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30 JAN 2022 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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02 FEB 2022 00:01

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06 FEB 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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 ☐

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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09 FEB 2022 00:01

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13 FEB 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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20 FEB 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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 ☐

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

02 MAR 2022 00:01

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06 MAR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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09 MAR 2022 00:01

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13 MAR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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 ☐

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

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20 MAR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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 ☐

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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 ☐

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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10 APR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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17 APR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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20 APR 2022 00:01

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24 APR 2022 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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27 APR 2022 00:01

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01 MAY 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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04 MAY 2022 00:01

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08 MAY 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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11 MAY 2022 00:01

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15 MAY 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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22 MAY 2022 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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25 MAY 2022 00:01

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29 MAY 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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12 JUN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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15 JUN 2022 00:01

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19 JUN 2022 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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22 JUN 2022 00:01

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26 JUN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**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 ☐

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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03 JUL 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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10 JUL 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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="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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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17 JUL 2022 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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20 JUL 2022 00:01

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24 JUL 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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31 JUL 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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07 AUG 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 <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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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"/>

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3542043

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:47:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		06 MAR 2021 22:36:25

US3542043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Dec 2020 16:07:57

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3542043

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Dec 2020 16:07:57

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Jan 2021 03:41:13

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542043

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Jan 2021 03:41:13

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Feb 2021 22:30:42

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542043

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Feb 2021 22:30:42

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 01:06:14

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542043

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 01:06:14

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 19:57:42

Generated On: 11 Aug 2021 22:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4



US3542043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 19:57:42

Generated On: 11 Aug 2021 22:47:42

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3542043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 19:57:42

Generated On: 11 Aug 2021 22:47:42

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.*

US3542043

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 19:57:42

Generated On: 11 Aug 2021 22:47:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 APR 2021

Collection time (00:00-23:59)

12:27 (24 HR)

Collection date and time (derived)

12 APR 2021 12:27

US3542043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 19:57:42

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3542043**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

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*

**US3542043**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 20:04:51

Generated On: 11 Aug 2021 22:47:42

Date of Contact	08 SEP 2020
Time of Contact	10:45
Date and Time of Contact (derived)	08 SEP 2020 10:45
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

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"/>



US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	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"/>

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Symptom Day

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

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

Date	12 SEP 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	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"/>

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Symptom Day

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



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

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

Date	13 SEP 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	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"/>

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Symptom Day

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	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"/>

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Symptom Day

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



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

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

Date	15 SEP 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	98.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input 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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Form: Symptom Log (5)

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	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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 17:32:21

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	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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 checked="" type="radio"/>
	Mild	<input 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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Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 17:32:21

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	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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

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"/>



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Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 17:32:21

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input 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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Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 17:32:21

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	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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	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"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

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"/>



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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input 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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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

	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"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

Symptom Day

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

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

Date	09 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

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

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Apr 2021 17:32:21

Generated On: 11 Aug 2021 22:47:42

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

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Sep 2020 04:16:21

Generated On: 11 Aug 2021 22:47:42

Date of Visit	11 SEP 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	15 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input checked="" 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)	1



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Jan 2021 02:40:40

Generated On: 11 Aug 2021 22:47:42

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Jan 2021 02:40:40

Generated On: 11 Aug 2021 22:47:42

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Jan 2021 02:40:40

Generated On: 11 Aug 2021 22:47:42

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Sep 2020 04:16:21

Generated On: 11 Aug 2021 22:47:42

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[Generate Next COVID-19 Assessment](#)

Yes ☐  
No ☒

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US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 16:19:21

Generated On: 11 Aug 2021 22:47:42

Date of Contact	08 SEP 2020
Time of Contact	10:45
Date and Time of Contact (derived)	08 SEP 2020 10:45
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Mar 2021 22:39:25

Generated On: 11 Aug 2021 22:47:42

Date of Visit	11 SEP 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	11 SEP 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

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 SEP 2020
Day 5	Yes	15 SEP 2020
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	Yes	1 OCT 2020
Day 28	Yes	13 OCT 2020

US3542043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 30 Sep 2020 22:36:55

Generated On: 11 Aug 2021 22:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	SICKD1



US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Sep 2020 22:36:55

Generated On: 11 Aug 2021 22:47:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	14:08 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:08
Height (xxx.x)	64 in
Weight (xxx.x)	165 lb
Temperature (xxx.x)	99.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Sep 2020 22:36:55

Generated On: 11 Aug 2021 22:47:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3542043

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 30 Sep 2020 22:36:55

Generated On: 11 Aug 2021 22:47:42

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 SEP 2020

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 11 Aug 2021 22:47:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:45
Height (xxx.x)	167 cm
Weight (xxx.x)	161 lb
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 OCT 2020

US3542043

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

Form: Visit Date

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

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

Visit date (dd MMM yyyy)	14 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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US3542043

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 22:39:25

Generated On: 11 Aug 2021 22:47:42

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 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> )	14 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

US3542043

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Jan 2021 20:40:46

Generated On: 11 Aug 2021 22:47:42

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3542043

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Jan 2021 20:40:46

Generated On: 11 Aug 2021 22:47:42

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)	14 JAN 2021
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 09:00
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3542043

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Jan 2021 20:40:46

Generated On: 11 Aug 2021 22:47:42

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)	14 JAN 2021
Time of assessment (00:00-23:59)	09:38 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 09:38
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	92 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3542043

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

Form: Physical Examination

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3542043

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

Form: Pregnancy Test

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	14 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)	

US3542043

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

Form: Exposure

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 09:08 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 09:08

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

US3542043

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

08:59 (24 HR)

Collection date and time (derived)

14 JAN 2021 08:59



US3542043

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	09:00
Collection Date and Time (derived)	14 JAN 2021 09:00

US3542043

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

Form: Continuing

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

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*

US3542043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3542043

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 17:00:41

Generated On: 11 Aug 2021 22:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 17:24:40

Generated On: 11 Aug 2021 22:47:42

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)	10 FEB 2021
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 10:22
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 17:24:40

Generated On: 11 Aug 2021 22:47:42

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	10 FEB 2021
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 11:25
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

US3542043

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 17:00:40

Generated On: 11 Aug 2021 22:47:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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



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Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 17:00:40

Generated On: 11 Aug 2021 22:47:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	10 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)	

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Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 17:00:40

Generated On: 11 Aug 2021 22:47:42

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) 10 FEB 2021

What was the treatment time? (00:00-23:59) 10:55 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 10:55

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

US3542043

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 17:00:40

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:40:07

Generated On: 11 Aug 2021 22:47:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3542043

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:40:07

Generated On: 11 Aug 2021 22:47:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 01:12:36

Generated On: 11 Aug 2021 22:47:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3542043

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Mar 2021 01:12:36

Generated On: 11 Aug 2021 22:47:42

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3542043

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 01:12:36

Generated On: 11 Aug 2021 22:47:42

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.*



US3542043

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 01:12:36

Generated On: 11 Aug 2021 22:47:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 MAR 2021

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

08 MAR 2021 12:20

US3542043

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Sep 2020 15:16:09

Generated On: 11 Aug 2021 22:47:42

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

AEID	USA-US084-2020-MRNA-1273-P30 1000002
Adverse event	SYMPTOMATIC COVID 19
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	07 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

---

PARTICIPANT HAD MILD SYMPTOMS OF RHINORRHEA, NASAL CONGESTION, POST-NASAL DRIP AND NON-PRODUCTIVE COUGH STARTING ON 07SEP2020. NO FEVER, CHILLS, DYSPNEA, MYALGIAS, ARTHRALGIAS, LOSS OF TASTE/SMELL, OR GI SYMPTOMS. ILLNESS VISIT DAY 1 CONDUCTED ON 11SEP2020; NP SWAB FROM THAT DAY WAS SARS-COV-2 PCR NEGATIVE. SALIVA COLLECTED ON 13SEP 2020 ALSO PCR NEGATIVE. SYMPTOMS RESOLVED ON 14 SEP2020. SALIVA COLLECTED ON 15SEP2020 BUT FURTHER TELEMEDICINE VISITS AND SALIVA COLLECTIONS DISCONTINUED THEREAFTER DUE TO REPORT OF NEGATIVE DAY 1 NP SWAB PCR RECEIVED ON 16SEP2020. HOWEVER, LATE ON 23SEP2020, THE CONVALESCENT DAY 5 (15SEP2020) SALIVA SAMPLE WAS REPORTED AS POSITIVE FOR SARS-COV-2. MULTIPLE EPIP EXCHANGES BETWEEN PI AND PPD/MODERNA ON 24-25SEP2020 RESULTED IN THE DECISION THAT THIS WOULD BE CONSIDERED A POSITIVE

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

---

SYMPTOMATIC COVID-19 CASE,  
WITH THE DAY 1 ILLNESS VISIT  
CONSIDERED AS 11SEP2020.  
SINCE SYMPTOMS HAD  
RESOLVED ON 14SEP2020  
(CONFIRMED VIA PHONE ON  
24SEP2020), ADDITIONAL  
TELEMEDICINE VISITS WERE  
NOT WARRANTED. A  
CONVALESCENT DAY 21  
SALIVA SAMPLE WILL BE  
COLLECTED ON 01OCT2020 AS  
WELL AS A CONVALESCENT  
DAY 29 VISIT ON 08OCT2020.  
THE SECOND DOSE OF  
VACCINE/PLACEBO WILL NOT  
BE ADMINISTERED. IT SHOULD  
BE NOTED THAT THE PI STILL  
CONSIDERS THE POSITIVE  
CONVALESCENT DAY 5 SALIVA  
PCR RESULT TO BE A FALSE  
POSITIVE GIVEN THE  
COMPLETE LACK OF  
CORRELATION BETWEEN  
CLINICAL  
PRESENTATION/EVOLUTION,  
AND THE LABORATORY  
RESULTS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

---

---

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

AEID

Adverse event

LOW GRADE SQUAMOUS  
INTRAEPITHELIAL LESION OF  
CERVIX

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)

6 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

AEID

Adverse event

DOG BITE TO THE FACE

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)

24 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

31 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Jan 2021 18:10:34

Generated On: 11 Aug 2021 22:47:42

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 27 Aug 2020 15:39:41

Generated On: 11 Aug 2021 22:47:42

---

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

Yes ☒

No ☐

---

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

---

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

	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 MAR 2019	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

Name of Medication CETIRIZINE HCl

Prophylaxis Yes ☐  
No ☒

Indication DOG ALLERGY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

Name of Medication MIRENA

Prophylaxis Yes ☒  
No ☐

Indication CONTRACEPTION

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	UN FEB 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	03 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 SEP 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"/>

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE TO THE FACE

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 31 Jan 2021 19:17:23

Generated On: 11 Aug 2021 22:47:42

	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)	27 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Nov 2020 21:46:19

Generated On: 11 Aug 2021 22:47:42

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 20 Nov 2020 04:10:14

Generated On: 11 Aug 2021 22:47:42

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
03 NOV 2020	COLPOSCOPY	Diagnostic	

US3542043

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 20 Nov 2020 04:10:14

Generated On: 11 Aug 2021 22:47:42

Date of dosing discontinuation (dd MMM yyyy) 05 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify



US3542043

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:47:42

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 ☐

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

SAEID	USA-US084-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

SAEID	USA-US084-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/SEP/2020 12:31
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

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

SAEID	USA-US084-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/OCT/2020 13:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 14 Oct 2020 02:21:42

Generated On: 11 Aug 2021 22:47:42

SAEID	USA-US084-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/OCT/2020 12:18
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

Audit

US3542043 (Prod: George Washington University)

**US3542043**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:47:42**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:51:00
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'US3542043'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:49:37

US3542043

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:35:36



US3542043

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:49:38

US3542043

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Clinic (Clinic)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:35:36

**US3542043**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'SCRN'	System	24 Aug 2020 13:35:36

US3542043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:42

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered (b) (6) 1993'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:49:39

**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '26'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38

**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'YEARS'	System	25 Aug 2020 17:23:38

**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '26'	System	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:42

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Female (F)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38
	(b) (4)	



US3542043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38

**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38
	(b) (4)	

**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38

**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38
	(b) (4)	

US3542043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:23:38

**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:23:38

**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38

US3542043

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:42

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38
	(b) (4)	



**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38

**US3542043**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:47:42**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38

US3542043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:42

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '24 Aug 2020'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:42

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'Aug 2020'	System	24 Aug 2020 13:36:04

**US3542043**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:47:42**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '2020'	System	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Amendment 2 (2)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:42

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:42

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04



US3542043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:49:38

US3542043

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'l'	System	24 Aug 2020 13:36:11

US3542043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:47:42

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:11

US3542043

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:47:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:06

US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:24:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:24:38
Data point term sent to Coder	System	25 Aug 2020 17:23:09
User entered 'migraines'	Taylor Ladson (b) (4)	25 Aug 2020 17:22:36

US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'un UNK 2011'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:36



US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:36

US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:36

**US3542043**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:36
	(b) (4)	

**US3542043**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:36

**US3542043**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'Jan 2011'	System	25 Aug 2020 17:22:36

**US3542043**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '2011'	System	25 Aug 2020 17:22:36

US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:42

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	25 Aug 2020 17:22:36

**US3542043**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	25 Aug 2020 17:22:36



US3542043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergic to dogs - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:08:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:08:10
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
Data point term sent to Coder	System (b) (4)	26 Aug 2020 18:40:02
Coding entries removed.	Hannah Yellin (b) (4)	26 Aug 2020 18:39:07
User entered 'ALLERGIES (DOGS)' reason for change: Data Entry Error	Hannah Yellin (b) (4)	26 Aug 2020 18:39:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergic to dogs - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 17:24:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 17:24:59
Data point term sent to Coder	System	25 Aug 2020 17:23:10
User entered 'Allergic to dogs'	Taylor Ladson (b) (4)	25 Aug 2020 17:22:54

US3542043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'un Jul 2020'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:54

US3542043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:54

**US3542043**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:54

**US3542043**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:42**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:54
	(b) (4)	

US3542043

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:22:54

**US3542043**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'Jul 2020'	System	25 Aug 2020 17:22:54

**US3542043**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '2020'	System	25 Aug 2020 17:22:54



**US3542043**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	25 Aug 2020 17:22:54

**US3542043**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	25 Aug 2020 17:22:54

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Systolic murmur - version MedDRA\23.0.	(b) (4) Coders Import (b) (4)	25 Aug 2020 17:24:36
User coded data point as Term Coded data point by User: Coders System - version MedDRA\23.0.	Coders Import (b) (4)	25 Aug 2020 17:24:36
Data point term sent to Coders System	System	25 Aug 2020 17:23:10
User entered 'systolic murmur'	Taylor Ladson (b) (4)	25 Aug 2020 17:23:05
	(b) (4)	

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:42

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'un UNK 2008'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:05

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:05

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User closed query 'Per CDM: Please review the status of this MH as the duration is unexpected for this Investigation. Note, procedures/surgeries/Investigations typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:20:16
Query 'Per CDM: Please review the status of this MH as the duration is unexpected for this Investigation. Note, procedures/surgeries/Investigations typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' answered with 'A systolic murmur would not be expected to have an end date without any intervention. This is ongoing' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	06 Nov 2020 20:49:03
User opened query 'Per CDM: Please review the status of this MH as the duration is unexpected for this Investigation. Note, procedures/surgeries/Investigations typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:40:11
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:39:41
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 17:23:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 17:23:10
User entered 'Yes (Y)' reason for change: Per Query Resolution	Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:23:10
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 17:23:05
User entered empty.	Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:23:05

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:42

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:05
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:05



**US3542043**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'Jan 2008'	System	25 Aug 2020 17:23:05

**US3542043**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '2008'	System	25 Aug 2020 17:23:05

**US3542043**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	25 Aug 2020 17:23:05

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:42

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	25 Aug 2020 17:23:05

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01

**US3542043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '08:52'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01

**US3542043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '24 Aug 2020 08:52'	System	25 Aug 2020 17:25:01



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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '167' cm	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01
DataPoint set to visible.	(b) (4) System	24 Aug 2020 13:36:11

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '159' lb	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01
DataPoint set to visible.	(b) (4) System	24 Aug 2020 13:36:11

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
Amendment Manager: User entered '25.91442'	System	17 Sep 2020 00:20:46
User entered '25.9'	System	25 Aug 2020 17:25:01
DataPoint set to visible.	System	24 Aug 2020 13:36:11

**US3542043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'kg/m2'	System	25 Aug 2020 17:25:01
DataPoint set to visible.	System	24 Aug 2020 13:36:11

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01



**US3542043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'bpm'	System	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'breaths/min'	System	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01

**US3542043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'mmHg'	System	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:01

**US3542043**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'mmHg'	System	25 Aug 2020 17:25:01

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11



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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11

US3542043

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User closed query 'Per CDM: As per CCG, If participant is screened and dosed on the same day: please record Physical Examination as performed at Screening and not performed at Day 1. Please reconcile and update accordingly.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	13 Nov 2020 08:05:25
Query 'Per CDM: As per CCG, If participant is screened and dosed on the same day: please record Physical Examination as performed at Screening and not performed at Day 1. Please reconcile and update accordingly.' answered with 'updated' (Site from DM).	David Diemert (b) (4)	12 Nov 2020 21:46:19
Signature has been broken.	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	11 Nov 2020 18:26:33
User opened query 'Per CDM: As per CCG, If participant is screened and dosed on the same day: please record Physical Examination as performed at Screening and not performed at Day 1. Please reconcile and update accordingly.' (Site from DM). User signature succeeded.	(b) (4)	
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 05:50:38
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4)	
	System	26 Aug 2020 18:39:38
	System	25 Aug 2020 17:24:20
	Taylor Ladson (b) (4)	25 Aug 2020 17:24:20
	(b) (4)	

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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System). Signature has been broken.	(b) (4) System	11 Nov 2020 18:26:26
	Elissa Malkin (b) (4)	11 Nov 2020 18:26:26
User entered '24 Aug 2020' reason for change: Per Query Resolution	(b) (4)	
	Elissa Malkin (b) (4)	11 Nov 2020 18:26:26
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System). User signature succeeded.	(b) (4) System	11 Nov 2020 18:26:02
	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty; reason for change Data Entry Error	(b) (4)	
	Hannah Yellin (b) (4)	26 Aug 2020 18:39:38
User entered '24 Aug 2020'	(b) (4)	
	Taylor Ladson (b) (4)	25 Aug 2020 17:24:20
	(b) (4)	

US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '24 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:54

US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:42

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:54

US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:42

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:54

US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:42

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:54

**US3542043**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:47:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:54



US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:42

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:54

US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:23:54

US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:47:42

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:23:54

US3542043

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User closed query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	(b) (4) System	25 Aug 2020 17:24:13
User entered 'Yes (Y)' reason for change: Per Query Resolution	Taylor Ladson (b) (4)	25 Aug 2020 17:24:13
User opened query 'Was the pregnancy test performed is No, however data has been provided below. Please correct.' (Site from System).	(b) (4) System	25 Aug 2020 17:24:07
User entered 'No (N)'	Taylor Ladson (b) (4)	25 Aug 2020 17:24:07

US3542043

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:24:07

**US3542043**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Urine (URINE)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:24:07

**US3542043**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Negative (NEGATIVE)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:24:07

US3542043

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:24:07



**US3542043**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:24:07

**US3542043**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:24:07

**US3542043**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	25 Aug 2020 17:24:07

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

**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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

**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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

**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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58



US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

**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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

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**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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

**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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

**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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

**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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Economist'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

**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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'l'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

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 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58
	(b) (4)	



US3542043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:27:28

**US3542043**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:27:28

US3542043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Clinic (Clinic)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:27:28

US3542043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'VISIT1'	System	25 Aug 2020 17:27:28

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:14:21

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:42

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '107170'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:14:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:42

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:14:21

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:42

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32



US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:42

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:42

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:42

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:42

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	28 Sep 2020 19:39:38
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:39:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:24:45

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33



US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:25:33

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 Aug 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '08:52'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:25:33

**US3542043**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered '24 Aug 2020 08:52'	System	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '98.3' F	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '56'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'bpm'	System	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '15'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'breaths/min'	System	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '107'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'mmHg'	System	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '62'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'mmHg'	System	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered missing code ND - Not Done.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:25:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:26:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '10:37'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered '24 Aug 2020 10:37'	System	25 Aug 2020 17:26:08



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '98.5' F	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '49'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:26:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'bpm'	System	25 Aug 2020 17:26:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '14'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'breaths/min'	System	25 Aug 2020 17:26:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '99'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'mmHg'	System	25 Aug 2020 17:26:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '66'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'mmHg'	System	25 Aug 2020 17:26:08

US3542043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	11 Nov 2020 18:27:00
	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	11 Nov 2020 18:27:00
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	25 Aug 2020 17:27:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	11 Nov 2020 18:27:00
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Elissa Malkin (b) (4)	11 Nov 2020 18:27:00
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '24 Aug 2020'	Taylor Ladson (b) (4)	25 Aug 2020 17:27:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:20

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:20
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Pregnancy Test

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[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:20

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
User closed query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 06:13:33
Query 'Per CDM: Response is required at this field. Please consider to update else clarify.' answered with 'Response added' (Site from DM).	Hannah Yellin (b) (4)	10 Sep 2020 17:25:35
Signature has been broken.	(b) (4)	10 Sep 2020 17:25:25
User entered 'No (N)' reason for change: Data Entry Error	Hannah Yellin (b) (4)	10 Sep 2020 17:25:25
User opened query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 07:51:50
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	Taylor Ladson (b) (4)	25 Aug 2020 17:26:20

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**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:20

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:20
	(b) (4)	

**US3542043**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered empty.	System	25 Aug 2020 17:26:20

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Hira Qadir (b) (4) (b) (4)	24 Aug 2020 14:11:48

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Hira Qadir (b) (4) (b) (4)	24 Aug 2020 14:11:48

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Hira Qadir (b) (4)	24 Aug 2020 14:11:48



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 14:11:48

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 Aug 2020'	(b) (4) Hira Qadir (b) (4) (b) (4)	24 Aug 2020 14:11:48

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '10:06'	(b) (4) Hira Qadir (b) (4) (b) (4)	24 Aug 2020 14:11:48

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered '24 Aug 2020 10:06'	System	24 Aug 2020 14:11:48

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) Hira Qadir (b) (4) (b) (4)	24 Aug 2020 14:11:48

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'ONCE'	System	24 Aug 2020 14:11:48

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 14:11:48

US3542043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:52



US3542043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:52

US3542043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '09:18'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:26:52

**US3542043**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered '24 Aug 2020 09:18'	System	25 Aug 2020 17:26:52

US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '24 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:27:08

US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:27:08

US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:27:08

US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '09:24'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:27:08

**US3542043**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered '24 Aug 2020 09:24'	System	25 Aug 2020 17:27:08



US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:27:08

US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:27:08

US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:27:08

**US3542043**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered empty.	System	25 Aug 2020 17:27:08

US3542043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:29

**US3542043**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'I'	System	25 Aug 2020 17:26:29

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:39:35', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'ab57738b-a641-43dc-98c3-833e9fa8866a' User entered 'Yes (Y)'	System	24 Aug 2020 14:39:52
	System	24 Aug 2020 14:39:52



US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:39:40', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'ab57738b-a641-43dc-98c3-833e9fa8866a' User entered '98.5'	System	24 Aug 2020 14:39:52
	System	24 Aug 2020 14:39:52

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:39:46', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'ab57738b-a641-43dc-98c3-833e9fa8866a' User entered 'No (N)'	System	24 Aug 2020 14:39:52
	System	24 Aug 2020 14:39:52

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:39:51', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'ab57738b-a641-43dc-98c3-833e9fa8866a' User entered '24 Aug 2020 10:39'	System	24 Aug 2020 14:39:52
	System	24 Aug 2020 14:39:52

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '24 Aug 2020 10:26'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '24 Aug 2020 12:56'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:31:25', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8addae1e-4b01-4105-b427-9979f31b4560' User entered 'Yes (Y)'	System	25 Aug 2020 00:31:43
	System	25 Aug 2020 00:31:43

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:31:33', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8addae1e-4b01-4105-b427-9979f31b4560' User entered '98.7'	System	25 Aug 2020 00:31:43
	System	25 Aug 2020 00:31:43



US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:31:36', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8addae1e-4b01-4105-b427-9979f31b4560'	System	25 Aug 2020 00:31:43
User entered 'No (N)'	System	25 Aug 2020 00:31:43

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:31:39', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8addae1e-4b01-4105-b427-9979f31b4560'	System	25 Aug 2020 00:31:43
User entered '24 Aug 2020 20:31'	System	25 Aug 2020 00:31:43

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '24 Aug 2020 13:51'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 2'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:56', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '9e73b0de-3d45-4702-91a8-8ecc777d6a09' User entered 'Yes (Y)'	System	26 Aug 2020 01:03:08
	System	26 Aug 2020 01:03:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:03:00', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '9e73b0de-3d45-4702-91a8-8ecc777d6a09' User entered '98.7'	System	26 Aug 2020 01:03:08
	System	26 Aug 2020 01:03:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:03:03', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '9e73b0de-3d45-4702-91a8-8ecc777d6a09' User entered 'No (N)'	System	26 Aug 2020 01:03:08
	System	26 Aug 2020 01:03:08



US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:03:07', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '9e73b0de-3d45-4702-91a8-8ecc777d6a09' User entered '25 Aug 2020 21:03'	System	26 Aug 2020 01:03:08
	System	26 Aug 2020 01:03:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 3'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09



US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 4'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-28T01:13:16', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '87a53a91-f558-4e36-932b-d4875ad42cf3' User entered 'Yes (Y)'	System	28 Aug 2020 05:13:27
	System	28 Aug 2020 05:13:27

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-28T01:13:21', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '87a53a91-f558-4e36-932b-d4875ad42cf3' User entered '97.7'	System	28 Aug 2020 05:13:27
	System	28 Aug 2020 05:13:27

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-28T01:13:23', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '87a53a91-f558-4e36-932b-d4875ad42cf3' User entered 'No (N)'	System	28 Aug 2020 05:13:27
	System	28 Aug 2020 05:13:27



US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-28T01:13:26', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '87a53a91-f558-4e36-932b-d4875ad42cf3' User entered '28 Aug 2020 01:13'	System	28 Aug 2020 05:13:27
	System	28 Aug 2020 05:13:27

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 5'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09



US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 6'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:10:28', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '69dfb7af-1410-4eb0-ae03-22cacce971ce' User entered 'Yes (Y)'	System	30 Aug 2020 01:10:49
	System	30 Aug 2020 01:10:49

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:10:32', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '69dfb7af-1410-4eb0-ae03-22cacce971ce' User entered '97.2'	System	30 Aug 2020 01:10:49
	System	30 Aug 2020 01:10:49

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:10:34', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '69dfb7af-1410-4eb0-ae03-22cacce971ce'	System	30 Aug 2020 01:10:49
User entered 'No (N)'	System	30 Aug 2020 01:10:49



US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:10:36', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '69dfb7af-1410-4eb0-ae03-22cacce971ce' User entered '29 Aug 2020 21:10'	System	30 Aug 2020 01:10:49
	System	30 Aug 2020 01:10:49

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 7'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:05:56', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2d978935-bc14-4eaa-a8a9-ca4db6d30528' User entered 'Yes (Y)'	System	31 Aug 2020 01:06:08
	System	31 Aug 2020 01:06:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:00', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2d978935-bc14-4eaa-a8a9-ca4db6d30528' User entered '98.2'	System	31 Aug 2020 01:06:08
	System	31 Aug 2020 01:06:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:02', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2d978935-bc14-4eaa-a8a9-ca4db6d30528'	System	31 Aug 2020 01:06:08
User entered 'No (N)'	System	31 Aug 2020 01:06:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:04', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2d978935-bc14-4eaa-a8a9-ca4db6d30528' User entered '30 Aug 2020 21:06'	System	31 Aug 2020 01:06:08
	System	31 Aug 2020 01:06:08



US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:02', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '11b15e07-3f6c-4341-bd66-c1471c6df121'	System	24 Aug 2020 14:40:28
User entered 'None (1)'	System	24 Aug 2020 14:40:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:09', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '11b15e07-3f6c-4341-bd66-c1471c6df121'	System	24 Aug 2020 14:40:28
User entered 'No (N)'	System	24 Aug 2020 14:40:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:16', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '11b15e07-3f6c-4341-bd66-c1471c6df121'	System	24 Aug 2020 14:40:28
User entered 'No (N)'	System	24 Aug 2020 14:40:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:21', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '11b15e07-3f6c-4341-bd66-c1471c6df121' User entered 'None (1)'	System	24 Aug 2020 14:40:28
	System	24 Aug 2020 14:40:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:26', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '11b15e07-3f6c-4341-bd66-c1471c6df121' User entered '24 Aug 2020 10:40'	System	24 Aug 2020 14:40:28
	System	24 Aug 2020 14:40:28



US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '24 Aug 2020 10:26'	System	24 Aug 2020 14:11:48

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '24 Aug 2020 12:56'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:31:46', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'c2d03fcd-3d37-4343-a68b-02da37858c89'	System	25 Aug 2020 00:32:19
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 00:32:19

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:31:54', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'c2d03fcd-3d37-4343-a68b-02da37858c89'	System	25 Aug 2020 00:32:19
User entered 'No (N)'	System	25 Aug 2020 00:32:19

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:03', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'c2d03fcd-3d37-4343-a68b-02da37858c89'	System	25 Aug 2020 00:32:19
User entered 'No (N)'	System	25 Aug 2020 00:32:19

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:07', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'c2d03fcd-3d37-4343-a68b-02da37858c89'	System	25 Aug 2020 00:32:19
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 00:32:19

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:13', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'c2d03fcd-3d37-4343-a68b-02da37858c89' User entered '24 Aug 2020 20:32'	System	25 Aug 2020 00:32:19
	System	25 Aug 2020 00:32:19



**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '24 Aug 2020 13:51'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 2'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:01', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd70b9355-aa26-461c-9697-9568655e250f' User entered 'None (1)'	System	26 Aug 2020 01:02:28
	System	26 Aug 2020 01:02:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:07', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd70b9355-aa26-461c-9697-9568655e250f' User entered 'No (N)'	System	26 Aug 2020 01:02:28
	System	26 Aug 2020 01:02:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:10', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd70b9355-aa26-461c-9697-9568655e250f' User entered 'No (N)'	System	26 Aug 2020 01:02:28
	System	26 Aug 2020 01:02:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:24', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd70b9355-aa26-461c-9697-9568655e250f'	System	26 Aug 2020 01:02:28
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 01:02:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:26', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd70b9355-aa26-461c-9697-9568655e250f' User entered '25 Aug 2020 21:02'	System	26 Aug 2020 01:02:28
	System	26 Aug 2020 01:02:28



**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 3'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:35', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'eccc0aac-690a-4c18-801a-f7b734b7fc38' User entered 'None (1)'	System	27 Aug 2020 01:06:47
	System	27 Aug 2020 01:06:47

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:37', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'eccc0aac-690a-4c18-801a-f7b734b7fc38'	System	27 Aug 2020 01:06:47
User entered 'No (N)'	System	27 Aug 2020 01:06:47

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:39', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'eccc0aac-690a-4c18-801a-f7b734b7fc38'	System	27 Aug 2020 01:06:47
User entered 'No (N)'	System	27 Aug 2020 01:06:47

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:41', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'eccc0aac-690a-4c18-801a-f7b734b7fc38'	System	27 Aug 2020 01:06:47
User entered 'None (1)'	System	27 Aug 2020 01:06:47

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:44', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'eccc0aac-690a-4c18-801a-f7b734b7fc38' User entered '26 Aug 2020 21:06'	System	27 Aug 2020 01:06:47
	System	27 Aug 2020 01:06:47



US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 4'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:15:30', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '9de2d56e-3d0b-4587-b83a-80428d30b119'	System	28 Aug 2020 03:15:54
User entered 'None (1)'	System	28 Aug 2020 03:15:54

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:15:41', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '9de2d56e-3d0b-4587-b83a-80428d30b119'	System	28 Aug 2020 03:15:54
User entered 'No (N)'	System	28 Aug 2020 03:15:54

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:15:43', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '9de2d56e-3d0b-4587-b83a-80428d30b119' User entered 'No (N)'	System	28 Aug 2020 03:15:54
	System	28 Aug 2020 03:15:54

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:15:45', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '9de2d56e-3d0b-4587-b83a-80428d30b119'	System	28 Aug 2020 03:15:54
User entered 'None (1)'	System	28 Aug 2020 03:15:54

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:15:50', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '9de2d56e-3d0b-4587-b83a-80428d30b119' User entered '27 Aug 2020 23:15'	System	28 Aug 2020 03:15:54
	System	28 Aug 2020 03:15:54



US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 5'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09



US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 6'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:11:45', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '5e0df446-342b-4e78-a87d-38bda829f1d2'	System	30 Aug 2020 01:12:04
User entered 'None (1)'	System	30 Aug 2020 01:12:04

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:11:48', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '5e0df446-342b-4e78-a87d-38bda829f1d2'	System	30 Aug 2020 01:12:04
User entered 'No (N)'	System	30 Aug 2020 01:12:04

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:11:49', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '5e0df446-342b-4e78-a87d-38bda829f1d2'	System	30 Aug 2020 01:12:04
User entered 'No (N)'	System	30 Aug 2020 01:12:04



US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:11:58', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '5e0df446-342b-4e78-a87d-38bda829f1d2'	System	30 Aug 2020 01:12:04
User entered 'None (1)'	System	30 Aug 2020 01:12:04

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:12:01', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '5e0df446-342b-4e78-a87d-38bda829f1d2' User entered '29 Aug 2020 21:12'	System	30 Aug 2020 01:12:04
	System	30 Aug 2020 01:12:04

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 7'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:07', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'aa0f4844-fae2-4fac-9037-b052c354cef8'	System	31 Aug 2020 01:06:17
User entered 'None (1)'	System	31 Aug 2020 01:06:17

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:09', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'aa0f4844-fae2-4fac-9037-b052c354cef8'	System	31 Aug 2020 01:06:17
User entered 'No (N)'	System	31 Aug 2020 01:06:17

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:10', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'aa0f4844-fae2-4fac-9037-b052c354cef8'	System	31 Aug 2020 01:06:17
User entered 'No (N)'	System	31 Aug 2020 01:06:17



US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:11', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'aa0f4844-fae2-4fac-9037-b052c354cef8'	System	31 Aug 2020 01:06:17
User entered 'None (1)'	System	31 Aug 2020 01:06:17

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:13', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'aa0f4844-fae2-4fac-9037-b052c354cef8'	System	31 Aug 2020 01:06:17
User entered '30 Aug 2020 21:06'	System	31 Aug 2020 01:06:17

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:34', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7b93488d-859a-4219-9e7a-064650e66c4f'	System	24 Aug 2020 14:41:05
User entered 'No interference with activity (1)'	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:43', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7b93488d-859a-4219-9e7a-064650e66c4f' User entered 'None (0)'	System	24 Aug 2020 14:41:05
	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:48', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7b93488d-859a-4219-9e7a-064650e66c4f' User entered 'None (0)'	System	24 Aug 2020 14:41:05
	System	24 Aug 2020 14:41:05



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:50', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7b93488d-859a-4219-9e7a-064650e66c4f' User entered 'None (0)'	System	24 Aug 2020 14:41:05
	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:52', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7b93488d-859a-4219-9e7a-064650e66c4f' User entered 'None (0)'	System	24 Aug 2020 14:41:05
	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:55', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7b93488d-859a-4219-9e7a-064650e66c4f' User entered 'None (0)'	System	24 Aug 2020 14:41:05
	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:40:58', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7b93488d-859a-4219-9e7a-064650e66c4f' User entered 'No (N)'	System	24 Aug 2020 14:41:05
	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T10:41:02', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7b93488d-859a-4219-9e7a-064650e66c4f' User entered '24 Aug 2020 10:41'	System	24 Aug 2020 14:41:05
	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '24 Aug 2020 10:26'	System	24 Aug 2020 14:11:48

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '24 Aug 2020 12:56'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:11:48



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:23', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fe3c6518-c55e-4b9f-b27f-513093c8431f' User entered 'None (0)'	System	25 Aug 2020 00:32:39
	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:25', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fe3c6518-c55e-4b9f-b27f-513093c8431f' User entered 'None (0)'	System	25 Aug 2020 00:32:39
	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:27', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fe3c6518-c55e-4b9f-b27f-513093c8431f' User entered 'None (0)'	System	25 Aug 2020 00:32:39
	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:29', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fe3c6518-c55e-4b9f-b27f-513093c8431f' User entered 'None (0)'	System	25 Aug 2020 00:32:39
	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:31', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fe3c6518-c55e-4b9f-b27f-513093c8431f' User entered 'None (0)'	System	25 Aug 2020 00:32:39
	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:32', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fe3c6518-c55e-4b9f-b27f-513093c8431f' User entered 'None (0)'	System	25 Aug 2020 00:32:39
	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:35', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fe3c6518-c55e-4b9f-b27f-513093c8431f' User entered 'No (N)'	System	25 Aug 2020 00:32:39
	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-24T20:32:37', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fe3c6518-c55e-4b9f-b27f-513093c8431f' User entered '24 Aug 2020 20:32'	System	25 Aug 2020 00:32:39
	System	25 Aug 2020 00:32:39



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '24 Aug 2020 13:51'	System	24 Aug 2020 14:11:48

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 2'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:30', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2901a28b-0b93-4430-8dc5-ecf6d1468d98' User entered 'None (0)'	System	26 Aug 2020 01:02:51
	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:32', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2901a28b-0b93-4430-8dc5-ecf6d1468d98' User entered 'None (0)'	System	26 Aug 2020 01:02:51
	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:34', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2901a28b-0b93-4430-8dc5-ecf6d1468d98' User entered 'None (0)'	System	26 Aug 2020 01:02:51
	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:38', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2901a28b-0b93-4430-8dc5-ecf6d1468d98' User entered 'None (0)'	System	26 Aug 2020 01:02:51
	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:41', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2901a28b-0b93-4430-8dc5-ecf6d1468d98' User entered 'None (0)'	System	26 Aug 2020 01:02:51
	System	26 Aug 2020 01:02:51



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:43', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2901a28b-0b93-4430-8dc5-ecf6d1468d98' User entered 'None (0)'	System	26 Aug 2020 01:02:51
	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:45', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2901a28b-0b93-4430-8dc5-ecf6d1468d98'	System	26 Aug 2020 01:02:51
User entered 'No (N)'	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-25T21:02:49', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2901a28b-0b93-4430-8dc5-ecf6d1468d98' User entered '25 Aug 2020 21:02'	System	26 Aug 2020 01:02:51
	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 3'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:47', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '0ec50658-1b7b-4353-987c-5af24a68d564' User entered 'None (0)'	System	27 Aug 2020 01:06:57
	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:48', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '0ec50658-1b7b-4353-987c-5af24a68d564' User entered 'None (0)'	System	27 Aug 2020 01:06:57
	System	27 Aug 2020 01:06:57



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:49', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '0ec50658-1b7b-4353-987c-5af24a68d564' User entered 'None (0)'	System	27 Aug 2020 01:06:57
	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:50', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '0ec50658-1b7b-4353-987c-5af24a68d564' User entered 'None (0)'	System	27 Aug 2020 01:06:57
	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:51', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '0ec50658-1b7b-4353-987c-5af24a68d564' User entered 'None (0)'	System	27 Aug 2020 01:06:57
	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:52', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '0ec50658-1b7b-4353-987c-5af24a68d564' User entered 'None (0)'	System	27 Aug 2020 01:06:57
	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:53', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '0ec50658-1b7b-4353-987c-5af24a68d564' User entered 'No (N)'	System	27 Aug 2020 01:06:57
	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-26T21:06:56', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '0ec50658-1b7b-4353-987c-5af24a68d564' User entered '26 Aug 2020 21:06'	System	27 Aug 2020 01:06:57
	System	27 Aug 2020 01:06:57

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:11:48



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 4'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:15:56', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2e1a47bf-caef-4ec2-b4f8-443939fe5016' User entered 'None (0)'	System	28 Aug 2020 03:16:07
	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:15:57', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2e1a47bf-caef-4ec2-b4f8-443939fe5016' User entered 'None (0)'	System	28 Aug 2020 03:16:07
	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:15:58', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2e1a47bf-caef-4ec2-b4f8-443939fe5016' User entered 'None (0)'	System	28 Aug 2020 03:16:07
	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:15:59', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2e1a47bf-caef-4ec2-b4f8-443939fe5016' User entered 'None (0)'	System	28 Aug 2020 03:16:07
	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:16:00', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2e1a47bf-caef-4ec2-b4f8-443939fe5016' User entered 'None (0)'	System	28 Aug 2020 03:16:07
	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:16:01', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2e1a47bf-caef-4ec2-b4f8-443939fe5016' User entered 'None (0)'	System	28 Aug 2020 03:16:07
	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:16:02', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2e1a47bf-caef-4ec2-b4f8-443939fe5016' User entered 'No (N)'	System	28 Aug 2020 03:16:07
	System	28 Aug 2020 03:16:07



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-27T23:16:04', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2e1a47bf-caef-4ec2-b4f8-443939fe5016' User entered '27 Aug 2020 23:16'	System	28 Aug 2020 03:16:07
	System	28 Aug 2020 03:16:07

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 5'	System	24 Aug 2020 14:11:48

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:42**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:42**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 6'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:12:03', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'e094288a-a414-4bc5-8483-2292df0e6b8d' User entered 'None (0)'	System	30 Aug 2020 01:12:26
	System	30 Aug 2020 01:12:26



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:12:05', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'e094288a-a414-4bc5-8483-2292df0e6b8d' User entered 'None (0)'	System	30 Aug 2020 01:12:26
	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:12:07', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'e094288a-a414-4bc5-8483-2292df0e6b8d' User entered 'None (0)'	System	30 Aug 2020 01:12:26
	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:12:08', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'e094288a-a414-4bc5-8483-2292df0e6b8d' User entered 'None (0)'	System	30 Aug 2020 01:12:26
	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:12:16', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'e094288a-a414-4bc5-8483-2292df0e6b8d'	System	30 Aug 2020 01:12:26
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:12:18', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'e094288a-a414-4bc5-8483-2292df0e6b8d' User entered 'None (0)'	System	30 Aug 2020 01:12:26
	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:12:21', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'e094288a-a414-4bc5-8483-2292df0e6b8d' User entered 'No (N)'	System	30 Aug 2020 01:12:26
	System	30 Aug 2020 01:12:26

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-29T21:12:24', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'e094288a-a414-4bc5-8483-2292df0e6b8d' User entered '29 Aug 2020 21:12'	System	30 Aug 2020 01:12:26
	System	30 Aug 2020 01:12:26

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:11:48



**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 7'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:20', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd206996c-d0ba-4d43-a055-3ed23b8e6cc0'	System	31 Aug 2020 01:06:37
User entered 'No interference with activity (1)'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:24', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd206996c-d0ba-4d43-a055-3ed23b8e6cc0' User entered 'No interference with activity (1)'	System	31 Aug 2020 01:06:37
	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:25', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd206996c-d0ba-4d43-a055-3ed23b8e6cc0' User entered 'None (0)'	System	31 Aug 2020 01:06:37
	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:26', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd206996c-d0ba-4d43-a055-3ed23b8e6cc0' User entered 'None (0)'	System	31 Aug 2020 01:06:37
	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:28', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd206996c-d0ba-4d43-a055-3cd23b8e6cc0' User entered 'None (0)'	System	31 Aug 2020 01:06:37
	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:30', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd206996c-d0ba-4d43-a055-3ed23b8e6cc0' User entered 'None (0)'	System	31 Aug 2020 01:06:37
	System	31 Aug 2020 01:06:37



US3542043

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:33', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd206996c-d0ba-4d43-a055-3ed23b8e6cc0' User entered 'No (N)'	System	31 Aug 2020 01:06:37
	System	31 Aug 2020 01:06:37

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-08-30T21:06:35', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd206996c-d0ba-4d43-a055-3ed23b8e6cc0' User entered '30 Aug 2020 21:06'	System	31 Aug 2020 01:06:37
	System	31 Aug 2020 01:06:37

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:11:48

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	31 Aug 2020 01:06:37
User entered 'Day 8'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:47:42

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '31 Aug 2020 12:00'	System	31 Aug 2020 01:06:37



US3542043

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	31 Aug 2020 01:06:37
User entered 'Day 9'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:47:42

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 01:06:37

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	31 Aug 2020 01:06:37
User entered 'Day 8'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:47:42

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09



US3542043

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '31 Aug 2020 12:00'	System	31 Aug 2020 01:06:37

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	31 Aug 2020 01:06:37
User entered 'Day 9'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:47:42

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:47:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 01:06:37

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 01:06:37



US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	30 Aug 2020 01:12:26
User entered 'Day 8'	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:47:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	31 Aug 2020 01:06:37
User entered 'Day 9'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:47:42

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 14:31:09

US3542043

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:47:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09



**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 01:06:37

**US3542043**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:47:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 01:06:37

US3542043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:29:17
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	01 Sep 2020 15:52:04

US3542043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:29:17
User entered '31 Aug 2020'	(b) (4) Taylor Ladson (b) (4)	01 Sep 2020 15:52:04

US3542043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:29:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Ladson (b) (4)	01 Sep 2020 15:52:04

US3542043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:29:17
User entered empty.	(b) (4) Taylor Ladson (b) (4)	01 Sep 2020 15:52:04

US3542043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:29:17
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	01 Sep 2020 15:51:26

US3542043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'l'	System	01 Sep 2020 15:51:26



US3542043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	18 Sep 2020 17:22:28
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Ladson (b) (4)	18 Sep 2020 17:22:28
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
	(b) (4)	
User entered 'No (N)'	Madhu Balachandran	15 Sep 2020 17:55:55
	(b) (4)	

US3542043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	18 Sep 2020 17:22:28
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Taylor Ladson (b) (4)	18 Sep 2020 17:22:28
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	17 Sep 2020 04:16:59
	(b) (4)	
User entered empty.	Madhu Balachandran	15 Sep 2020 17:55:55
	(b) (4)	

US3542043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	18 Sep 2020 17:22:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Taylor Ladson (b) (4)	18 Sep 2020 17:22:28
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	17 Sep 2020 04:16:59
User entered empty.	(b) (4)	
	Madhu Balachandran	15 Sep 2020 17:55:55
	(b) (4)	

**US3542043**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	15 Sep 2020 17:55:55

US3542043

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	15 Sep 2020 17:55:58

**US3542043**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'I'	System	15 Sep 2020 17:55:58

**US3542043**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	15 Sep 2020 17:56:09

US3542043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
User entered '14 Sep 2020'	(b) (4) Madhu Balachandran (b) (4)	15 Sep 2020 17:56:09



US3542043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Madhu Balachandran (b) (4)	15 Sep 2020 17:56:09

**US3542043**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	15 Sep 2020 17:56:09

US3542043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	15 Sep 2020 17:56:16

US3542043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'I'	System	15 Sep 2020 17:56:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:32:18

US3542043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 11:14:18
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Date is correct.' (Site from System).	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:32:37
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	06 Oct 2020 19:32:18
User entered '05 Oct 2020'	Taylor Ladson (b) (4)	06 Oct 2020 19:32:18

US3542043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Clinic (Clinic)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:32:18

**US3542043**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'VISIT2'	System	06 Oct 2020 19:32:18



US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered '05 Oct 2020'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered '12:02'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered '05 Oct 2020 12:02'	System	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered '98.3' F	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Oral (Oral)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:16



US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered '48'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'bpm'	System	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered '14'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'breaths/min'	System	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered '105'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'mmHg'	System	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 06:46:44
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:45
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		06 Oct 2020 19:33:16
User entered '57'	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'mmHg'	System	06 Oct 2020 19:33:16



US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
Query 'Per CDM: Please confirm if Post Dose vitals were assessed since this is required per protocol' canceled (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:06:20
User opened query 'Per CDM: Please confirm if Post Dose vitals were assessed since this is required per protocol' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:05:21
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20



US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:33:20



US3542043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:31:46

US3542043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:31:46

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:59

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered '5 Oct 2020'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:59

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Urine (URINE)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:59

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Negative (NEGATIVE)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:59

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:59

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:59



**US3542043**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:33:59

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:33:59

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User closed query 'Per CDM: Was study treatment given is No. Please reconcile and update the Dosing discontinuation form accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:32:18
Query 'Per CDM: Was study treatment given is No. Please reconcile and update the Dosing discontinuation form accordingly. ' answered with 'Dosing discontinuation form has been updated.' (Site from DM).	Erika Faust (b) (4) (b) (4)	05 Nov 2020 20:10:19
User opened query 'Per CDM: Was study treatment given is No. Please reconcile and update the Dosing discontinuation form accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:30:58
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Oct 2020 02:53:49
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:31:40



US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered empty.	System	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:34:34

US3542043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered '5 Oct 2020'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:34:34

US3542043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered '12:14'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:34:34

**US3542043**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered '5 Oct 2020 12:14'	System	06 Oct 2020 19:34:34



US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 19:59:42
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted however, please confirm swab sample collected on 05OCT2020, per Preclarus report samples collected for the subject US3542043 on 05OCT2020 under Visit 2 Day 29 with accession number "1F602327614" and Requisition kit id "1F650405492". Please reconcile the data, if any subject id mismatch or visit mismatch and raise a data clarification form to Preclarus. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:05:18
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted however, please confirm swab sample collected on 05OCT2020, per Preclarus report samples collected for the subject US3542043 on 05OCT2020 under Visit 2 Day 29 with accession number "1F602327614" and Requisition kit id "1F650405492". Please reconcile the data, if any subject id mismatch or visit mismatch and raise a data clarification form to Preclarus. Else clarify, thank you.' answered with 'An empty vial was erroneously scanned in the lab. Sample was NOT collected.' (Site from DM).	David Diemert (b) (4) (b) (4)	07 Apr 2021 11:59:09
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted however, please confirm swab sample collected on 05OCT2020, per Preclarus report samples collected for the subject US3542043 on 05OCT2020 under Visit 2 Day 29 with accession number "1F602327614" and Requisition kit id "1F650405492". Please reconcile the data, if any subject id mismatch or visit mismatch and raise a data clarification form to Preclarus. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:41:21
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "NP swab was not collected at Visit 2 Day 29"; however, per PPD portal, swab sample is present for Visit 2 Day 29 on 05-OCT-2020 with accession number "1F602327614". Kindly confirm & update as appropriate if swab sample was collected or not, else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:59:00

US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "NP swab was not collected at Visit 2 Day 29"; however, per PPD portal, swab sample is present for Visit 2 Day 29 on 05-OCT-2020 with accession number "1F602327614". Kindly confirm & update as appropriate if swab sample was collected or not, else clarify.' answered with 'Swab sample was not collected. ' (Site from DM).	Hannah Yellin (b) (4)	10 Feb 2021 20:15:49
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "NP swab was not collected at Visit 2 Day 29"; however, per PPD portal, swab sample is present for Visit 2 Day 29 on 05-OCT-2020 with accession number "1F602327614". Kindly confirm & update as appropriate if swab sample was collected or not, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 08:04:05
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 05Oct2020 is reported under Visit 2 Day 29 visit in PPD Central lab. However in EDC this was not collected. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:54:58
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 05Oct2020 is reported under Visit 2 Day 29 visit in PPD Central lab. However in EDC this was not collected. Please reconcile. ' answered with 'NP swab was not collected at Visit 2 Day 29 ' (Site from DM).	Elissa Malkin (b) (4)	04 Nov 2020 20:22:57
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 05Oct2020 is reported under Visit 2 Day 29 visit in PPD Central lab. However in EDC this was not collected. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:55:10
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:34:24

US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 19:59:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4) (b) (4)	06 Oct 2020 19:34:24

US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 19:59:42
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:34:24

US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 19:59:42
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:34:24

**US3542043**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 19:59:42
User entered empty.	System	06 Oct 2020 19:34:24

US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 19:59:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4) (b) (4)	06 Oct 2020 19:34:24

US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 19:59:42
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:34:24



**US3542043**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:47:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 19:59:42
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered empty.	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:34:24

**US3542043**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 19:59:42
User entered empty.	System	06 Oct 2020 19:34:24

US3542043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	06 Oct 2020 19:34:06

US3542043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'I'	System	06 Oct 2020 19:34:06

**US3542043**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:20:22

**US3542043**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 18:20:22

**US3542043**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Oct 2020 18:20:22

**US3542043**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:20:22



US3542043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:20:30

**US3542043**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'l'	System	13 Oct 2020 18:20:30

**US3542043**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 18:15:33
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	11 Nov 2020 18:15:12

US3542043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 18:15:33
User entered '20 Oct 2020'	(b) (4) David Diemert (b) (4) (b) (4)	11 Nov 2020 18:15:12

US3542043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 18:15:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) David Diemert (b) (4) (b) (4)	11 Nov 2020 18:15:12

**US3542043**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 18:15:33
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	11 Nov 2020 18:15:12

US3542043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User closed query 'Per CDM: Please update the details for Safety Call form.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:58:39
Query 'Per CDM: Please update the details for Safety Call form.' answered with 'Updated.' (Site from DM).	David Diemert (b) (4)	11 Nov 2020 18:33:59
User opened query 'Per CDM: Please update the details for Safety Call form.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:38:52
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4) (b) (4)	27 Oct 2020 17:33:56

**US3542043**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'l'	System	27 Oct 2020 17:33:56



US3542043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 17:34:08

US3542043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
User entered '26 Oct 2020'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 17:34:08

US3542043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 17:34:08

US3542043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 17:34:08

US3542043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
User entered 'Yes (Y)'	(b) (4) DeEnna Wedding (b) (4)	27 Oct 2020 17:34:13

US3542043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'l'	System	27 Oct 2020 17:34:13

US3542043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:37:05

US3542043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '2 Nov 2020'	(b) (4) Erika Faust (b) (4)	04 Nov 2020 17:37:05



US3542043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:37:05

**US3542043**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'VISIT3'	System	04 Nov 2020 17:37:05

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User closed query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:29:59
Query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly. ' answered with 'Date has been updated.' (Site from DM).	Erika Faust (b) (4)	06 Nov 2020 14:33:26
User entered '02 Nov 2020' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 14:33:14
User opened query 'Per CDM: Per CCG, Date of assessment should be recorded in (dd-MMM-yyyy) format. Please review and update it accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:48:51
User entered '2 Nov 2020'	Erika Faust (b) (4)	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '09:07'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:37:40

**US3542043**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered '02 Nov 2020 09:07'	System	06 Nov 2020 14:33:14
User entered '2 Nov 2020 09:07'	System	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '98.4' F	(b) (4) Erika Faust (b) (4)	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4)	04 Nov 2020 17:37:40



**US3542043**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '45'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:37:40

**US3542043**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'bpm'	System	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '16'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'breaths/min'	System	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '107'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'mmHg'	System	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '70'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:37:40



US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'mmHg'	System	04 Nov 2020 17:37:40

**US3542043**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14

US3542043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	04 Nov 2020 17:37:46

US3542043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:37:46

US3542043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:14
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 02NOV2020. However, collection date is missing in GCL. Please confirm if 02NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 13:55:34
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 02NOV2020. However, collection date is missing in GCL. Please confirm if 02NOV2020 is correct date to update in GCL records. ' answered with '02Nov2020 is the correct date.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	18 Nov 2020 14:49:57
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 02NOV2020. However, collection date is missing in GCL. Please confirm if 02NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:51:11
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:38:01

US3542043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:14
User entered '2 Nov 2020'	(b) (4) Erika Faust (b) (4)	04 Nov 2020 17:38:01

US3542043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:14
User entered '09:24'	(b) (4) Erika Faust (b) (4)	04 Nov 2020 17:38:01



US3542043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered '2 Nov 2020 09:24'	System	04 Nov 2020 17:38:01

US3542043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	04 Nov 2020 17:38:05

**US3542043**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:28:14
User entered 'I'	System	04 Nov 2020 17:38:05

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 64'	System	24 Aug 2020 14:11:48

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43
Data entry locked.	System	24 Aug 2020 14:11:48
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 14:11:48

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:33:43
Data entry locked.	System	24 Aug 2020 14:11:48
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 71'	System	24 Aug 2020 14:11:48



US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

[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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-11-02T09:31:29', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7147cb37-f14c-41cc-b2fa-67305964fe11' User entered 'No (N)'	System	09 Nov 2020 15:35:17
	System	09 Nov 2020 15:35:17

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

Have you been exposed to someone with 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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-11-02T09:31:31', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7147cb37-f14c-41cc-b2fa-67305964fe11'	System	09 Nov 2020 15:35:17
User entered 'No (N)'	System	09 Nov 2020 15:35:17

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-11-02T09:31:34', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7147cb37-f14c-41cc-b2fa-67305964fe11' User entered '02 Nov 2020 09:31:34'	System	09 Nov 2020 15:35:17
	System	09 Nov 2020 15:35:17

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 14:11:48

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 14:11:48

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered 'Day 78'	System	24 Aug 2020 14:11:48

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

[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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-11-09T10:35:43', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8fb536ac-f262-47ca-a4f8-e097a1bade39'	System	09 Nov 2020 15:36:02
User entered 'Yes (Y)'	System	09 Nov 2020 15:36:02

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

Have you been exposed to someone with 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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-11-09T10:35:41', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8fb536ac-f262-47ca-a4f8-e097a1bade39'	System	09 Nov 2020 15:36:02
User entered 'No (N)'	System	09 Nov 2020 15:36:02



US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-11-09T10:35:40', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8fb536ac-f262-47ca-a4f8-e097a1bade39'	System	09 Nov 2020 15:36:02
User entered 'No (N)'	System	09 Nov 2020 15:36:02

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-11-09T10:35:40', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8fb536ac-f262-47ca-a4f8-e097a1bade39'	System	09 Nov 2020 15:36:02
User entered 'Yes (Y)'	System	09 Nov 2020 15:36:02

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Please 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 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-11-09T10:35:39', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8fb536ac-f262-47ca-a4f8-e097a1bade39'	System	09 Nov 2020 15:36:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 15:36:02

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-11-09T10:35:49', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '8fb536ac-f262-47ca-a4f8-e097a1bade39' User entered '09 Nov 2020 10:35:49'	System	09 Nov 2020 15:36:02
	System	09 Nov 2020 15:36:02

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 14:11:48

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:31:09
Data entry locked.	System	24 Aug 2020 14:11:48
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 14:11:48

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-12-10T08:11:21', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '51654575-7407-4e55-98dc-305a5bf41902'	System	21 Dec 2020 04:26:22
User entered 'No (N)'	System	21 Dec 2020 04:26:22

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-12-10T08:11:23', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '51654575-7407-4e55-98dc-305a5bf41902'	System	21 Dec 2020 04:26:22
User entered 'No (N)'	System	21 Dec 2020 04:26:22

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-12-10T08:11:26', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '51654575-7407-4e55-98dc-305a5bf41902'	System	21 Dec 2020 04:26:22
User entered '10 Dec 2020 08:11:26'	System	21 Dec 2020 04:26:22

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-12-20T23:26:19', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '76b5b925-3e93-486e-a51b-5ce2a614ba91'	System	21 Dec 2020 04:26:27
User entered 'No (N)'	System	21 Dec 2020 04:26:27

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-12-20T23:26:22', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '76b5b925-3e93-486e-a51b-5ce2a614ba91'	System	21 Dec 2020 04:26:27
User entered 'No (N)'	System	21 Dec 2020 04:26:27



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-12-20T23:26:25', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '76b5b925-3e93-486e-a51b-5ce2a614ba91' User entered '20 Dec 2020 23:26:25'	System	21 Dec 2020 04:26:27

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-12-24T09:28:24', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7249c382-770f-46c3-9fed-ca936866d12d' User entered 'No (N)'	System	05 Jan 2021 17:22:35
	System	05 Jan 2021 17:22:35

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-12-24T09:28:26', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7249c382-770f-46c3-9fed-ca936866d12d'	System	05 Jan 2021 17:22:35
User entered 'No (N)'	System	05 Jan 2021 17:22:35

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2020-12-24T09:28:28', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7249c382-770f-46c3-9fed-ca936866d12d' User entered '24 Dec 2020 09:28:28'	System	05 Jan 2021 17:22:35

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-01-14T09:21:25', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'aad4f2c7-5e29-4885-b1bb-abdbcd8581b0' User entered 'No (N)'	System	14 Jan 2021 18:27:33
	System	14 Jan 2021 18:27:33

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-01-14T09:21:33', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'aad4f2c7-5e29-4885-b1bb-abdbcd8581b0' User entered 'No (N)'	System	14 Jan 2021 18:27:33
	System	14 Jan 2021 18:27:33

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-01-14T09:21:39', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'aad4f2c7-5e29-4885-b1bb-abdbcd8581b0' User entered '14 Jan 2021 09:21:39'	System	14 Jan 2021 18:27:33
	System	14 Jan 2021 18:27:33

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-01-21T14:37:52', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2ab9ec31-0cd1-4979-845b-7d8e65144366'	System	21 Jan 2021 19:38:01
User entered 'No (N)'	System	21 Jan 2021 19:38:01

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-01-21T14:37:54', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2ab9ec31-0cd1-4979-845b-7d8e65144366'	System	21 Jan 2021 19:38:01
User entered 'No (N)'	System	21 Jan 2021 19:38:01



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-01-21T14:37:59', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2ab9ec31-0cd1-4979-845b-7d8e65144366' User entered '21 Jan 2021 14:37:59'	System	21 Jan 2021 19:38:01

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-02-05T20:17:42', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'f2a49c34-cfd-45f5-a347-acb8c567a18f' User entered 'No (N)'	System	11 Feb 2021 14:07:26
	System	11 Feb 2021 14:07:26



US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-02-05T20:17:46', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'f2a49c34-cfd-45f5-a347-acb8c567a18f' User entered 'No (N)'	System	11 Feb 2021 14:07:26
	System	11 Feb 2021 14:07:26

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-02-05T20:17:49', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'f2a49c34-cfd-45f5-a347-acb8c567a18f' User entered '05 Feb 2021 20:17:49'	System	11 Feb 2021 14:07:26
	System	11 Feb 2021 14:07:26

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-02-10T11:20:47', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd8e504bf-be24-47f8-841a-db72b7e83607' User entered 'No (N)'	System	11 Feb 2021 14:07:26
	System	11 Feb 2021 14:07:26

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-02-10T11:20:49', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd8e504bf-be24-47f8-841a-db72b7e83607'	System	11 Feb 2021 14:07:26
User entered 'No (N)'	System	11 Feb 2021 14:07:26

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-02-10T11:20:51', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd8e504bf-be24-47f8-841a-db72b7e83607' User entered '10 Feb 2021 11:20:51'	System	11 Feb 2021 14:07:26
	System	11 Feb 2021 14:07:26



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-02-18T13:38:04', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '5397982a-f534-422c-a178-21846ccb8ba9' User entered 'No (N)'	System	07 Mar 2021 03:36:11
	System	07 Mar 2021 03:36:11

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-02-18T13:38:05', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '5397982a-f534-422c-a178-21846ccb8ba9' User entered 'No (N)'	System	07 Mar 2021 03:36:11

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-02-18T13:38:07', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '5397982a-f534-422c-a178-21846ccb8ba9' User entered '18 Feb 2021 13:38:07'	System	07 Mar 2021 03:36:11
	System	07 Mar 2021 03:36:11

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-06T22:36:14', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'b1460e45-097e-4671-83d6-1760a2aed040'	System	07 Mar 2021 03:36:21
User entered 'No (N)'	System	07 Mar 2021 03:36:21

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:42

Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-06T22:36:16', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'b1460e45-097e-4671-83d6-1760a2aed040'	System	07 Mar 2021 03:36:21
User entered 'No (N)'	System	07 Mar 2021 03:36:21

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-06T22:36:18', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'b1460e45-097e-4671-83d6-1760a2aed040'	System	07 Mar 2021 03:36:21
User entered '06 Mar 2021 22:36:18'	System	07 Mar 2021 03:36:21

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-14T13:13:36', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fc2d2741-5dde-4564-b5d4-94431c32f652'	System	14 Mar 2021 17:13:42
User entered 'No (N)'	System	14 Mar 2021 17:13:42

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-14T13:13:38', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fc2d2741-5dde-4564-b5d4-94431c32f652'	System	14 Mar 2021 17:13:42
User entered 'No (N)'	System	14 Mar 2021 17:13:42

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-14T13:13:40', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'fc2d2741-5dde-4564-b5d4-94431c32f652' User entered '14 Mar 2021 13:13:40'	System	14 Mar 2021 17:13:42

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-20T11:38:31', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '1e795ae2-25ee-43d3-9fdf-a9d3111f96d3' User entered 'No (N)'	System	16 Apr 2021 13:29:54
	System	16 Apr 2021 13:29:54

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-20T11:38:43', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '1e795ae2-25ee-43d3-9fdf-a9d3111f96d3' User entered 'No (N)'	System	16 Apr 2021 13:29:54
	System	16 Apr 2021 13:29:54

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-20T11:38:46', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '1e795ae2-25ee-43d3-9fdf-a9d3111f96d3' User entered '20 Mar 2021 11:38:46'	System	16 Apr 2021 13:29:54
	System	16 Apr 2021 13:29:54

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-04-09T22:37:54-04:00', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2bde3603-e44a-4619-b934-5d1470c204bd' User entered 'No (N)'	System	16 Apr 2021 13:29:54
	System	16 Apr 2021 13:29:54

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-04-09T22:37:56-04:00', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2bde3603-e44a-4619-b934-5d1470c204bd'	System	16 Apr 2021 13:29:54
User entered 'No (N)'	System	16 Apr 2021 13:29:54

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-04-09T22:37:59-04:00', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '2bde3603-e44a-4619-b934-5d1470c204bd' User entered '09 Apr 2021 22:37:59'	System	16 Apr 2021 13:29:54
	System	16 Apr 2021 13:29:54

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-04-16T09:29:55-04:00', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd4b29a7c-3053-424a-a08f-f33fd26def4f' User entered 'No (N)'	System	16 Apr 2021 13:30:02
	System	16 Apr 2021 13:30:02

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Have you been exposed to someone with 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 (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-04-16T09:29:57-04:00', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd4b29a7c-3053-424a-a08f-f33fd26def4f' User entered 'No (N)'	System	16 Apr 2021 13:30:02
	System	16 Apr 2021 13:30:02

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-04-16T09:29:59-04:00', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd4b29a7c-3053-424a-a08f-f33fd26def4f' User entered '16 Apr 2021 09:29:59'	System	16 Apr 2021 13:30:02
	System	16 Apr 2021 13:30:02

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:33:43

**US3542043**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:33:43



**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:33:43

**US3542043**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:47:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:33:43

US3542043

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:47:42**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-06T22:36:23', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd5bb229e-5a82-48a1-9202-982ec948f860'	System	07 Mar 2021 03:36:28
User entered 'No (N)'	System	07 Mar 2021 03:36:28



**US3542043**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:53:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9DF115CD-BF67-4BAA-AFA1-37086FC4EF81)', Time: '2021-03-06T22:36:25', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: 'd5bb229e-5a82-48a1-9202-982ec948f860' User entered '06 Mar 2021 22:36:25'	System	07 Mar 2021 03:36:28
	System	07 Mar 2021 03:36:28

**US3542043**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:57
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	01 Dec 2020 19:31:50

US3542043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:57
User entered '30 Nov 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	01 Dec 2020 19:31:50

US3542043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	01 Dec 2020 19:31:50

US3542043

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:57
User entered empty.	(b) (4) Erika Faust (b) (4)	01 Dec 2020 19:31:50

US3542043

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User signature succeeded.	David Diemert (b) (4)	10 Dec 2020 16:07:57
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	01 Dec 2020 19:31:33

**US3542043**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:53:06
User entered 'I'	System	01 Dec 2020 19:31:33

**US3542043**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:41:55



US3542043

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '05 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:41:55

**US3542043**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:41:55

**US3542043**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:41:55

US3542043

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:41:59

**US3542043**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User entered 'l'	System	08 Jan 2021 21:41:59

**US3542043**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:30:42
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	02 Feb 2021 17:00:40

US3542043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:30:42
User entered '01 Feb 2021'	(b) (4) Hannah Yellin (b) (4)	02 Feb 2021 17:00:40
	(b) (4)	

US3542043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:30:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Hannah Yellin (b) (4)	02 Feb 2021 17:00:40



US3542043

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:30:42
User entered empty.	(b) (4) Hannah Yellin (b) (4)	02 Feb 2021 17:00:40

US3542043

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	04 Feb 2021 22:30:42
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	02 Feb 2021 17:00:45

**US3542043**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User entered 'l'	System	02 Feb 2021 17:00:45

**US3542043**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:06:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 21:29:01

**US3542043**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:06:14
User entered '01 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:29:01

**US3542043**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:06:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Mar 2021 21:29:01

**US3542043**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:06:14
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 21:29:01

**US3542043**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User signature succeeded.	David Diemert (b) (4)	05 Mar 2021 01:06:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 21:29:07



**US3542043**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:23:27
User entered 'l'	System	01 Mar 2021 21:29:07

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:53:56

US3542043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:53:56

US3542043

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:53:56

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 17:53:56

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14

US3542043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14



**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:54:14

US3542043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14

US3542043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14

US3542043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:54:14

US3542043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:54:14



US3542043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:54:14

US3542043

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:54:14

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 17:54:14

US3542043

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:55:01

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:47:42**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:55:01

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:42**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:55:29

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:42**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:55:29



**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:42**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered '12:27'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:55:29

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 12:27'	System	13 Apr 2021 17:55:29

US3542043

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	13 Apr 2021 19:57:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:55:41

**US3542043**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	13 Apr 2021 17:55:41

**US3542043**

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:15:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:17:54
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:09:23
User entered '08 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:05:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:42

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:15:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:48:16
User closed query 'As per Source Follow-up note, the safety call on 08Sept2020 was made at 10:45AM' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 19:48:15
Query 'As per Source Follow-up note, the safety call on 08Sept2020 was made at 10:45AM' answered with 'Per source document, participant was contacted on 08SEP2020 at 10:45AM.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 18:24:25
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 18:24:21
User entered '10:45' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 18:24:21
User opened query 'As per Source Follow-up note, the safety call on 08Sept2020 was made at 10:45AM' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:45:23
User closed query 'Per CDM: Please enter the best estimated time of contact.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 06:36:47
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:09:23
Query 'Per CDM: Please enter the best estimated time of contact.' answered with 'Data entered' (Site from DM).	Hannah Yellin (b) (4)	23 Sep 2020 16:18:49
User entered '08:30' reason for change: New Information	Hannah Yellin (b) (4)	23 Sep 2020 16:18:39
User opened query 'Per CDM: Please enter the best estimated time of contact.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:11:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 07:09:52
Query 'Data is required. Please complete.' answered with 'Time of contact not known' (Site from System).	Hannah Yellin (b) (4)	17 Sep 2020 21:17:16
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:05:43
User entered empty.	Hannah Yellin (b) (4)	17 Sep 2020 17:05:43

**US3542043**

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:47:42**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:15:53
User entered '08 Sep 2020 10:45'	System	02 Apr 2021 18:24:21
User entered '08 Sep 2020 08:30'	System	23 Sep 2020 16:18:39
User entered empty.	System	17 Sep 2020 17:05:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:42

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:15:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:17:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:09:23
User entered 'Safety Call (Safety Call)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:05:43



**US3542043**

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:47:42**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:15:53
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:17:58
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 03:09:23
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:05:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
	(b) (4)	
User entered 'Day 5 (Day 5)' reason for change:	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'Day 1 (Day 1)'	Hannah Yellin (b) (4)	17 Sep 2020 17:06:43
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '11 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '98'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered '%'	System	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '99.4' F	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43



US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43



US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:33
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
	(b) (4)	
User entered 'Day 6 (Day 6)' reason for change:	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'Day 2 (Day 2)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	



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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '12 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

**US3542043**

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '98'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered '%'	System	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '97.9' F	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:34
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change:	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'Day 3 (Day 3)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '13 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02



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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '98'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered '%'	System	17 Sep 2020 17:08:02

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '98.2' F	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02



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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02



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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:37
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:02

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
	(b) (4)	
User entered 'Day 8 (Day 8)' reason for change:	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'Day 4 (Day 4)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '14 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:47:42**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '99'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered '%'	System	17 Sep 2020 17:08:27



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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '98.4' F	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27



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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27



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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:40
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
	(b) (4)	
User entered 'Day 9 (Day 9)' reason for change:	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'Day 5 (Day 5)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '15 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '99'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered '%'	System	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '98.3' F	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53



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Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Form: Symptom Log (5)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	16 Oct 2020 18:11:27
User entered 'None (None)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	16 Oct 2020 18:11:27
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'Mild (Mild)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	16 Oct 2020 18:11:27
User entered 'None (None)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	16 Oct 2020 18:11:27
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'Mild (Mild)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:42
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:08:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
	(b) (4)	
User entered 'Day 10 (Day 10)' reason for change:	Hannah Yellin (b) (4)	29 Sep 2020 16:04:05
Data Entry Error	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'Day 6 (Day 6)'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 13OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 03:32:22
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 13OCT2020. Please reconcile or clarify.' answered with 'Nope. Why would there have to be additional symptoms just because we conducted the protocol-required Conval Visit Day 28?????' (Site from DM).	David Diemert (b) (4) (b) (4)	09 Nov 2020 21:50:18
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 13OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:07:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:16:10
User entered '16 Sep 2020'	Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '98'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered '%'	System	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '98.2' F	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52



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Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 16:09:49
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:09:52

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Day 1 (Day 1)'	(b) (4) Hannah Yellin (b) (4)	29 Sep 2020 16:02:51

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '07 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	29 Sep 2020 16:02:51

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User closed query 'Per CDM: Please verify that Symptom Log Line 7 in Covid-19 Assessment 08 Sep 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:02:45
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
Query 'Per CDM: Please verify that Symptom Log Line 7 in Covid-19 Assessment 08 Sep 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' answered with 'Corrected.' (Site from DM).	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:00:04
	(b) (4)	
DataPoint Un-verified.	David Diemert (b) (4)	20 Apr 2021 14:57:58
	(b) (4)	
Signature has been broken.	David Diemert (b) (4)	20 Apr 2021 14:57:58
	(b) (4)	
User entered '0' reason for change: Data Entry Error	David Diemert (b) (4)	20 Apr 2021 14:57:58
	(b) (4)	
User opened query 'Per CDM: Please verify that Symptom Log Line 7 in Covid-19 Assessment 08 Sep 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:52:40
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered '1'	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	



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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 14:57:58
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 14:57:58
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	David Diemert (b) (4)	20 Apr 2021 14:57:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered '%'	System	20 Apr 2021 14:57:58
User entered empty.	System	29 Sep 2020 16:02:51

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 14:57:58
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 14:57:58
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	David Diemert (b) (4)	20 Apr 2021 14:57:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User closed query 'Please confirm - per source 7-9Sep2020 subject had only congestion and runny nose. If correct please mark all other symptoms as 'none'.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 15:19:56
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
Query 'Please confirm - per source 7-9Sep2020 subject had only congestion and runny nose. If correct please mark all other symptoms as 'none'.' answered with 'Updated.' (Site from CRA).	David Diemert (b) (4)	03 Apr 2021 19:48:14
DataPoint Un-verified.	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
User opened query 'Please confirm - per source 7-9Sep2020 subject had only congestion and runny nose. If correct please mark all other symptoms as 'none'.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 19:47:24
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User closed query 'As per source note dated 08Sept2020, Subject reported congestion, runny nose and watery eyes on 07Sep2020. Phone call on 09Sept2020 confirms continuation of rhinorrhea, post nasal drip and mild cough. Please confirm and update these symptoms on symptom logs for 07Sep2020-10Sep2020.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 19:45:13
User signature succeeded.	David Diemert (b) (4)	02 Apr 2021 16:54:13
Query 'As per source note dated 08Sept2020, Subject reported congestion, runny nose and watery eyes on 07Sep2020. Phone call on 09Sept2020 confirms continuation of rhinorrhea, post nasal drip and mild cough. Please confirm and update these symptoms on symptom logs for 07Sep2020-10Sep2020.' answered with 'Mild nasal congestion and rhinorrhea entered.' (Site from CRA).	(b) (4)	
Signature has been broken.	Caroline Thoreson (b) (4)	02 Apr 2021 16:30:21
User entered 'Mild (Mild)' reason for change: Per Query Resolution	(b) (4)	
User opened query 'As per source note dated 08Sept2020, Subject reported congestion, runny nose and watery eyes on 07Sep2020. Phone call on 09Sept2020 confirms continuation of rhinorrhea, post nasal drip and mild cough. Please confirm and update these symptoms on symptom logs for 07Sep2020-10Sep2020.' (Site from CRA).	Caroline Thoreson (b) (4)	02 Apr 2021 16:30:21
User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 16:09:12
User entered empty.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	02 Apr 2021 16:54:13
Signature has been broken.	(b) (4)	
	Caroline Thoreson (b) (4)	02 Apr 2021 16:30:21
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	02 Apr 2021 16:30:21
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	



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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:20:53
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:19:32
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:47:59
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:47:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User closed query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 3 (10Sep2020) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 08:48:06
Query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 3 (10Sep2020) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' answered with 'Done.' (Site from DM).	David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:22
User opened query 'Per CDM: Per sponsor review, please verify data and add entry for Symptom Day 3 (10Sep2020) to Symptom Log. If Not Done, please check Not Done for the applicable Symptom Day and Date.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 22:39:10
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:36:56
User entered 'Day 4 (Day 4)'	Hannah Yellin (b) (4) (b) (4)	29 Sep 2020 16:03:31

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '10 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	29 Sep 2020 16:03:31

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:01:30
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:01:30
User entered '0' reason for change: Per Query Resolution	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:01:30
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '1'	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:01:00
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:01:00
User entered missing code ND - Not Done; reason for	(b) (4)	
change Per Query Resolution	David Diemert (b) (4)	20 Apr 2021 15:01:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered '%'	System	20 Apr 2021 15:01:00
User entered empty.	System	29 Sep 2020 16:03:31



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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User closed query 'Per CDM: Please verify that Symptom Log Line 8 in Covid-19 Assessment 08 Sep 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:03:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
Query 'Per CDM: Please verify that Symptom Log Line 8 in Covid-19 Assessment 08 Sep 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' answered with 'Corrected' (Site from DM).	David Diemert (b) (4)	20 Apr 2021 15:02:30
DataPoint Un-verified.	David Diemert (b) (4)	20 Apr 2021 15:01:00
Signature has been broken.	David Diemert (b) (4)	20 Apr 2021 15:01:00
User entered missing code ND - Not Done; reason for change Per Query Resolution	David Diemert (b) (4)	20 Apr 2021 15:01:00
User opened query 'Per CDM: Please verify that Symptom Log Line 8 in Covid-19 Assessment 08 Sep 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:50:12
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User closed query 'Please confirm. Per source 10Sep2020 subject had only runny nose, nasal congestion, and cough. Please update other symptoms to none if appropriate.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 15:20:23
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
Query 'Please confirm. Per source 10Sep2020 subject had only runny nose, nasal congestion, and cough. Please update other symptoms to none if appropriate.' answered with 'Updated.' (Site from CRA).	David Diemert (b) (4)	03 Apr 2021 19:49:35
DataPoint Un-verified.	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
User opened query 'Please confirm. Per source 10Sep2020 subject had only runny nose, nasal congestion, and cough. Please update other symptoms to none if appropriate.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 19:48:06
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	02 Apr 2021 16:54:13
Signature has been broken.	(b) (4)	
	Caroline Thoreson (b) (4)	02 Apr 2021 16:31:55
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	02 Apr 2021 16:31:55
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	



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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	02 Apr 2021 16:54:13
Signature has been broken.	(b) (4)	
	Caroline Thoreson (b) (4)	02 Apr 2021 16:31:55
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	02 Apr 2021 16:31:55
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	02 Apr 2021 16:54:13
Signature has been broken.	(b) (4)	
	Caroline Thoreson (b) (4)	02 Apr 2021 16:31:55
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	02 Apr 2021 16:31:55
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:21:07
User signature succeeded.	David Diemert (b) (4)	03 Apr 2021 20:04:52
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	03 Apr 2021 19:49:20
User entered 'None (None)' reason for change: Per	(b) (4)	
Query Resolution	David Diemert (b) (4)	03 Apr 2021 19:49:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:03:31
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Day 2 (Day 2)'	(b) (4) Hannah Yellin (b) (4)	29 Sep 2020 16:09:40

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '08 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	29 Sep 2020 16:09:40

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User closed query 'Per CDM: Please verify that Symptom Log Line 9 in Covid-19 Assessment 08 Sep 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 05:14:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
Query 'Per CDM: Please verify that Symptom Log Line 9 in Covid-19 Assessment 08 Sep 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' answered with 'Updated.' (Site from DM).	(b) (4) David Diemert (b) (4)	20 Apr 2021 15:04:46
DataPoint Un-verified.	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4) David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered '0' reason for change: Per Query Resolution	(b) (4) David Diemert (b) (4)	20 Apr 2021 15:04:23
User opened query 'Per CDM: Please verify that Symptom Log Line 9 in Covid-19 Assessment 08 Sep 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 10:51:33
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '1'	(b) (4) Hannah Yellin (b) (4)	29 Sep 2020 16:09:40

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	David Diemert (b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered '%'	System	20 Apr 2021 15:04:23
User entered empty.	System	29 Sep 2020 16:09:40

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	David Diemert (b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	



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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	



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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	02 Apr 2021 16:54:13
Signature has been broken.	(b) (4)	
	Caroline Thoreson (b) (4)	02 Apr 2021 16:32:48
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	02 Apr 2021 16:32:48
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	02 Apr 2021 16:54:13
Signature has been broken.	(b) (4)	
	Caroline Thoreson (b) (4)	02 Apr 2021 16:32:48
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Caroline Thoreson (b) (4)	02 Apr 2021 16:32:48
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered empty.	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:04:37
User signature succeeded.	David Diemert (b) (4)	20 Apr 2021 17:32:21
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	20 Apr 2021 15:04:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Apr 2021 15:04:23
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	Hannah Yellin (b) (4)	29 Sep 2020 16:09:40
	(b) (4)	

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Form: Symptom Log (10)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered 'Day 3 (Day 3)'	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07



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Form: Symptom Log (10)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered '09 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Form: Symptom Log (10)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered 'l'	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
User entered empty.	System	15 Mar 2021 12:42:07

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4)	
	David Diemert (b) (4)	15 Mar 2021 12:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4)	
	David Diemert (b) (4)	15 Mar 2021 12:42:07
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07



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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:42

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:25
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 19:46:16
User signature succeeded.	David Diemert (b) (4)	15 Mar 2021 15:53:41
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	15 Mar 2021 12:42:07

**US3542043**

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '11 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:10:14

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Form: COVID Diagnostic Test

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[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:10:14

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Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 05:37:05
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Convalescent Day 5 saliva test reported as PCR positive by Viracor despite Day 1 NP PCR and Day 3 saliva PCR being negative.' (Site from System).	David Diemert (b) (4)	29 Sep 2020 03:49:03
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	29 Sep 2020 03:48:11
Signature has been broken.	David Diemert (b) (4)	29 Sep 2020 03:48:11
User entered 'Yes (Y)' reason for change: Data Entry Error	David Diemert (b) (4)	29 Sep 2020 03:48:11
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'No (N)'	Hannah Yellin (b) (4)	17 Sep 2020 17:10:14



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Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15SEP2020 is recorded under Covid-19 Assessment in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 04:39:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15SEP2020 is recorded under Covid-19 Assessment in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'It's unbelievable the number of queries we've received related to this. Once and for all, this participant tested NEGATIVE by NP PCR on Illness Day 1 but before that result became available, we had already collected the Day 5 saliva, which turned out to be positive for COVID-19 by PCR. The dates are correct. Please stop querying this. ' (Site from DM).	David Diemert (b) (4) (b) (4)	05 Apr 2021 14:17:30
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15SEP2020 is recorded under Covid-19 Assessment in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 03:23:24
User closed query 'Per GCL Lab Reconciliation: Saliva: Requrey 1: "Type of test performed" = "Saliva test" dated 15SEP2020, which is updated under this visit, however the same saliva sample dated 15SEP2020 is updated under Illness visit in PPD central Lab, please verify the sample and visit and update under appropriate visit.Thanks ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 05:38:06

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[Date of Test](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1: "Type of test performed" = "Saliva test" dated 15SEP2020, which is updated under this visit, however the same saliva sample dated 15SEP2020 is updated under Illness visit in PPD central Lab, please verify the sample and visit and update under appropriate visit.Thanks  ' answered with 'An additional COVID contact form has been added to capture the original negative swab.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:51:53
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1: "Type of test performed" = "Saliva test" dated 15SEP2020, which is updated under this visit, however the same saliva sample dated 15SEP2020 is updated under Illness visit in PPD central Lab, please verify the sample and visit and update under appropriate visit.Thanks	(b) (4), (b) (6)	22 Feb 2021 05:29:32
' (Site from DM). User closed query 'Per GCL Lab Reconciliation: Saliva: Per PPD Central Lab Saliva dated 15SEP2020 is updated under Illness visit, however the same is updated under covid -19 visit in EDC. Please verify the visit and update, else clarify.Thanks' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 05:29:32
Query 'Per GCL Lab Reconciliation: Saliva: Per PPD Central Lab Saliva dated 15SEP2020 is updated under Illness visit, however the same is updated under covid -19 visit in EDC. Please verify the visit and update, else clarify.Thanks' answered with 'I do not understand this query despite re-reading it multiple times. Please clarify.' (Site from DM).	David Diemert (b) (4) (b) (4)	17 Feb 2021 14:04:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Per PPD Central Lab Saliva dated 15SEP2020 is updated under Illness visit, however the same is updated under covid -19 visit in EDC. Please verify the visit and update, else clarify.Thanks' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 07:58:07
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54

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Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:48:11
	(b) (4)	
User entered '15 Sep 2020' reason for change: Data Entry Error	David Diemert (b) (4)	29 Sep 2020 03:48:11
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '11 Sep 2020'	Hannah Yellin (b) (4)	17 Sep 2020 17:10:14
	(b) (4)	

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Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
User closed query 'Per GCL Lab reconciliation re-query: SWAB: Response noted. However, please reconfirm if the swab sample was collected on 11Sep2020. If yes, please enter data in EDC even if the result is negative.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:33:43
Query 'Per GCL Lab reconciliation re-query: SWAB: Response noted. However, please reconfirm if the swab sample was collected on 11Sep2020. If yes, please enter data in EDC even if the result is negative.' answered with 'If we enter the result from 11SEP2020, there will be no record of the positive saliva PCR from 15SEP2020 in the EDC. Please confirm that you prefer that there is NO record of a positive PCR on this participant in the EDC. We are happy to comply but this request seems extremely bizarre to us.' (Site from DM).	David Diemert (b) (4) (b) (4)	03 Jan 2021 17:52:10
User opened query 'Per GCL Lab reconciliation re-query: SWAB: Response noted. However, please reconfirm if the swab sample was collected on 11Sep2020. If yes, please enter data in EDC even if the result is negative.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:13:05
User closed query 'Per GCL Lab Reconciliation: GCL has a Nasopharyngeal Swab sample and COVID PCR Swab sample with a Collection Date of 11SEP2020, however, these sample do not appear in the CRF. Please clarify and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:13:05
Query 'Per GCL Lab Reconciliation: GCL has a Nasopharyngeal Swab sample and COVID PCR Swab sample with a Collection Date of 11SEP2020, however, these sample do not appear in the CRF. Please clarify and reconcile as appropriate.' answered with 'The NP swab COVID PCR from 11SEP2020 was NEGATIVE. Only the Day 5 convalescent saliva sample PCR was positive.' (Site from DM).	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:12:42

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Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

Type of Test Performed

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: GCL has a Nasopharyngeal Swab sample and COVID PCR Swab sample with a Collection Date of 11SEP2020, however, these sample do not appear in the CRF. Please clarify and reconcile as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:57:57
User signature succeeded.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
Signature has been broken.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	(b) (4)	29 Sep 2020 03:48:11
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 03:48:11
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	17 Sep 2020 17:10:14

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Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:10:14

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Form: COVID Diagnostic Test

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:10:14

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Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:10:14



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Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	17 Sep 2020 17:10:14

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:33
User entered '1'	System	29 Sep 2020 03:48:11
User entered '0'	System	17 Sep 2020 17:10:14

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:42

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:42

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:42

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53



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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:42

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:42

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53



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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Generated On: 11 Aug 2021 22:47:42

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Generated On: 11 Aug 2021 22:47:42

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Sep 2020 03:50:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 03:50:08
User entered 'No (N)' reason for change: Data Entry Error	David Diemert (b) (4)	29 Sep 2020 03:50:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Sep 2020 03:49:53
User entered empty.	System	29 Sep 2020 03:49:53
	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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Generated On: 11 Aug 2021 22:47:42

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	



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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:42

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

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Generated On: 11 Aug 2021 22:47:42

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:42

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:42

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53



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Generated On: 11 Aug 2021 22:47:42

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections as it appears response is missing and update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 05:31:08
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections as it appears response is missing and update accordingly.' answered with 'OK' (Site from DM).	David Diemert (b) (4) (b) (4)	13 Jan 2021 20:57:43
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections as it appears response is missing and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 23:00:14
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:08:01
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:40
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:57:38
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:57:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:57:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
	(b) (4)	
User entered empty.	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53



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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:08:01
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:40
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
	(b) (4)	
User entered empty.	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:08:01
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:40
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
	(b) (4)	
User entered empty.	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:08:01
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:40
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
	(b) (4)	
User entered empty.	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53



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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:08:01
User signature succeeded.	David Diemert (b) (4)	15 Jan 2021 02:40:40
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 20:56:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
	(b) (4)	
User entered empty.	David Diemert (b) (4)	29 Sep 2020 03:49:53
	(b) (4)	

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Generated On: 11 Aug 2021 22:47:42

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:35:04
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

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[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:16:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:45
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:44:49
User entered 'Yes (Y)'	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:44:13
	(b) (4)	

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**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID-19 Contact**

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[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:33
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:43
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered '08 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:48:56

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:42

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:33
User signature succeeded.	David Diemert (b) (4)	05 Apr 2021 16:19:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:22:32
User closed query 'as per Source Follow-up note safety call on 08Sept2020 phone call was made at 10:45AM. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 15:22:19
Query 'as per Source Follow-up note safety call on 08Sept2020 phone call was made at 10:45AM. Please verify and update.' answered with 'Corrected.' (Site from CRA).	David Diemert (b) (4) (b) (4)	03 Apr 2021 19:45:43
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Apr 2021 19:45:28
User entered '10:45' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	03 Apr 2021 19:45:28
User opened query 'as per Source Follow-up note safety call on 08Sept2020 phone call was made at 10:45AM. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	02 Apr 2021 15:56:04
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Mar 2021 22:39:25
User entered '08:30'	Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:48:56



**US3542043**

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:47:42**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:33
User entered '08 Sep 2020 10:45'	System	03 Apr 2021 19:45:28
User entered '08 Sep 2020 08:30'	System	12 Mar 2021 16:48:56

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:42

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:33
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:44
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered 'Safety Call (Safety Call)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:48:56

**US3542043**

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:47:42**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:33
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:45
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:48:56

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered '11 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:50:17

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:50:17

**US3542043**

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:47:42**

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:50:17

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered '11 Sep 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:50:17

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Hannah Yellin (b) (4)	12 Mar 2021 16:50:17



US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:50:17

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

[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)	03 May 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered 'No (N)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:50:17

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:50:17

**US3542043**

**Folder: Covid-19 Assessment 08 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:47:42**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:27
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:54:30
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered empty.	(b) (4) Hannah Yellin (b) (4) (b) (4)	12 Mar 2021 16:50:17

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:42

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:17:27
User entered '0'	System	12 Mar 2021 16:50:17

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:25

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:25

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '13 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:25



**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '15 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
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	29 Sep 2020 04:08:05
User entered 'No (N)' reason for change: Data Entry Error	David Diemert (b) (4)	29 Sep 2020 04:08:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Sep 2020 04:07:38
	David Diemert (b) (4)	29 Sep 2020 04:07:38
	(b) (4)	

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:47:42**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
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	29 Sep 2020 04:08:05
User entered 'No (N)' reason for change: Data Entry Error	David Diemert (b) (4)	29 Sep 2020 04:08:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Sep 2020 04:07:38
	David Diemert (b) (4)	29 Sep 2020 04:07:38
	(b) (4)	



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:47:42

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
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	29 Sep 2020 04:08:05
User entered 'No (N)' reason for change: Data Entry Error	David Diemert (b) (4)	29 Sep 2020 04:08:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Sep 2020 04:07:38
	David Diemert (b) (4)	29 Sep 2020 04:07:38
	(b) (4)	

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered empty.	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:47:42**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
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	05 Oct 2020 01:36:27
User entered 'Yes (Y)' reason for change: New Information	David Diemert (b) (4)	05 Oct 2020 01:36:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Sep 2020 04:07:38
	David Diemert (b) (4)	29 Sep 2020 04:07:38
	(b) (4)	

**US3542043**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '1 Oct 2020' reason for change: New Information	(b) (4) David Diemert (b) (4)	05 Oct 2020 01:36:27
User entered empty.	(b) (4) David Diemert (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:47:42

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13OCT2020 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:53:36
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13OCT2020 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Per site processing lab, no date was listed in Preclarus for some samples. A request was made to update this information.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	22 Jan 2021 18:44:19
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13OCT2020 is recorded under Illness Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 08:07:29
User accepted default value 'Day 28 (Day 28)'	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38



US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:47:42

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
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	13 Oct 2020 15:35:24
User entered 'Yes (Y)' reason for change: New Information	Hannah Yellin (b) (4)	13 Oct 2020 15:35:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	29 Sep 2020 04:07:38
	David Diemert (b) (4)	29 Sep 2020 04:07:38
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:47:42

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is reported under Convalescence Visit Day 28 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.	(b) (4), (b) (6)	02 Dec 2020 06:45:50
' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is reported under Convalescence Visit Day 28 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.	Hannah Yellin (b) (4) (b) (4)	01 Dec 2020 14:11:21
' answered with 'Sample was collected on 13Oct2020. Site processing lab is addressing this is in the lab data management system.' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08OCT2020 is reported under Convalescence Visit Day 28 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.	(b) (4), (b) (6)	12 Nov 2020 07:53:00
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 02:21:42
User entered '13 Oct 2020' reason for change: New Information	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:35:24
User entered empty.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:25:01
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:23:15

**US3542043**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:25:01
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '11 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:23:15

US3542043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:25:01
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Clinic (Clinic)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:23:15

US3542043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
User entered 'SICKD1'	System	29 Sep 2020 04:23:15

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '11 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 13:48:38



**US3542043**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '14:08'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
User entered '11 Sep 2020 14:08'	System	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '64' in	(b) (4) David Diemert (b) (4)	29 Sep 2020 13:48:38
DataPoint set to visible.	(b) (4) System	29 Sep 2020 04:23:15

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '165' lb	(b) (4) David Diemert (b) (4)	29 Sep 2020 13:48:38
DataPoint set to visible.	(b) (4) System	29 Sep 2020 04:23:15

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '99.4' F	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Oral (Oral)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 13:48:38

**US3542043**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 13:48:38
	(b) (4)	

**US3542043**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '73'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 13:48:38



US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
User entered 'bpm'	System	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '16'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
User entered 'breaths/min'	System	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '108'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 13:48:38

**US3542043**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
User entered 'mmHg'	System	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 17:51:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '69'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 13:48:38

**US3542043**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
User entered 'mmHg'	System	29 Sep 2020 13:48:38

**US3542043**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05



**US3542043**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05

US3542043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:47
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:23:29

US3542043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:47
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '11 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:23:29

US3542043

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:47:42

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:52
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Yes (Y)'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:23:45

**US3542043**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:40:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:16:52
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '11 Sep 2020'	(b) (4) David Diemert (b) (4) (b) (4)	29 Sep 2020 04:23:45

**US3542043**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:08
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:33:53

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:08
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '13 Oct 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:33:53

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:08
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Clinic (Clinic)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:33:53



**US3542043**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User entered 'SICKD28'	System	13 Oct 2020 15:33:53

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered 'Yes (Y)'	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '13 Oct 2020'	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33

**US3542043**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '08:45'	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33

**US3542043**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User entered '13 Oct 2020 08:45'	System	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 15:10:48
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 19:40:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Oct 2020 19:40:48
DataPoint Un-verified.	Hannah Yellin (b) (4)	19 Oct 2020 19:40:48
User entered '167' cm reason for change: Per Query Resolution	Hannah Yellin (b) (4)	19 Oct 2020 19:40:48
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 15:34:33
User entered empty.	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33
DataPoint set to visible.	System	13 Oct 2020 15:33:53

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '161' lb	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33
DataPoint set to visible.	(b) (4) System	13 Oct 2020 15:33:53

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '98.8' F	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33



US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered 'Oral (Oral)'	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33

**US3542043**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered empty.	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '62'	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User entered 'bpm'	System	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '14'	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User entered 'breaths/min'	System	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '112'	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User entered 'mmHg'	System	13 Oct 2020 15:34:33



US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '69'	Hannah Yellin (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
User entered 'mmHg'	System	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21

**US3542043**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:50
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:51

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:17:50
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '13 Oct 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:51

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:47:42

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 13 OCT 2020 is recorded under Convalescence Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM). User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 13 OCT 2020 is recorded under Convalescence Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:27:22
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 03:48:31
User signature succeeded.	(b) (4), (b) (6)	14 Oct 2020 18:18:00
User entered 'Yes (Y)'	David Diemert (b) (4) (b) (4) Hannah Yellin (b) (4) (b) (4)	14 Oct 2020 02:21:42 13 Oct 2020 15:35:03

**US3542043**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:47:42**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:56:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:18:00
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '13 Oct 2020'	(b) (4) Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:35:03



**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:58:21

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:58:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[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 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Clinic (Clinic)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:58:21

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 17:58:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:58:49

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:47:42**

[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 20:04:11
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:26:50

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:58:49

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:47:42**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	12 Mar 2021 22:39:25
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:26:50



US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:58:49

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Placebo (Placebo)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:58:49

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 08:14:01
User entered 'Placebo (Placebo)'	Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:58:49

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 08:14:01
User entered 'Placebo (Placebo)'	Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:58:49

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:47:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:58:49

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:47:42**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'I'	System	15 Jan 2021 17:58:49

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'I'	System	15 Jan 2021 17:58:49

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46



US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	15 Jan 2021 18:00:46
DataPoint set to visible.	System	15 Jan 2021 17:58:49

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	15 Jan 2021 18:00:46
DataPoint set to visible.	System	15 Jan 2021 17:58:49

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46



US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '09:00'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '14 Jan 2021 09:00'	System	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '98.5' F reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	15 Jan 2021 18:01:19
User entered '98.7' F	(b) (4)	
	Erika Faust (b) (4)	15 Jan 2021 18:00:46
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '56' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:01:10
User entered '48'	Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'bpm'	System	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '12' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:01:10
User entered '16'	Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46



US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'breaths/min'	System	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '122' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:01:10
User entered '92'	Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'mmHg'	System	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System (b) (4)	15 Jan 2021 18:01:10
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	15 Jan 2021 18:01:10
User entered '77' reason for change: Data Entry Error	Erika Faust (b) (4)	15 Jan 2021 18:01:10
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	15 Jan 2021 18:00:46
User entered '56'	Erika Faust (b) (4)	15 Jan 2021 18:00:46

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'mmHg'	System	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered missing code ND - Not Done.	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	15 Jan 2021 18:00:46
DataPoint set to visible.	System	15 Jan 2021 17:58:49



US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '09:38'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '14 Jan 2021 09:38'	System	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '98.7' F reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:01:54
User entered '98.5' F	Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered 'Oral (Oral)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered empty.	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:00:46



US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '48' reason for change: Data Entry Error	(b) (4)	
	Erika Faust (b) (4)	15 Jan 2021 18:01:54
User entered '56'	(b) (4)	
	Erika Faust (b) (4)	15 Jan 2021 18:00:46
	(b) (4)	

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'bpm'	System	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '16' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:01:54
User entered '12'	Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'breaths/min'	System	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
User entered '92' reason for change: Data Entry Error	(b) (4) Erika Faust (b) (4)	15 Jan 2021 18:01:54
User entered '122'	Erika Faust (b) (4) (b) (4)	15 Jan 2021 18:00:46

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'mmHg'	System	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 14:19:34
User signature succeeded.	David Diemert (b) (4)	25 Jan 2021 20:40:46
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Not clinically significant/not an AE' (Site from System).	(b) (4) Elissa Malkin (b) (4)	25 Jan 2021 19:50:07
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		15 Jan 2021 18:01:54
User entered '56' reason for change: Data Entry Error	Erika Faust (b) (4)	15 Jan 2021 18:01:54
User entered '77'	Erika Faust (b) (4)	15 Jan 2021 18:00:46

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'mmHg'	System	15 Jan 2021 18:00:46



US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:59:44

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:59:44

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:59:37

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:59:37

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Urine (URINE)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:59:37

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Negative (NEGATIVE)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:59:37

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:59:37

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:59:37



**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:59:37

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered empty.	System	15 Jan 2021 17:59:37

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:59:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:59:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

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 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered empty.	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:59:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'mRNA-1273'	System	15 Jan 2021 17:59:21
DataPoint set to visible.	System	15 Jan 2021 17:58:49

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:59:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '09:08'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:59:21



**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:47:42**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '14 Jan 2021 09:08'	System	15 Jan 2021 17:59:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:59:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'ONCE'	System	15 Jan 2021 17:59:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 17:59:21

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:58:15

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:58:15

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '08:59'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:58:15

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '14 Jan 2021 08:59'	System	15 Jan 2021 17:58:15



US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:58:05

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:47:42**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '14 Jan 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:58:05

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:47:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '09:00'	(b) (4) Erika Faust (b) (4) (b) (4)	15 Jan 2021 17:58:05

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:47:42**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered '14 Jan 2021 09:00'	System	15 Jan 2021 17:58:05

US3542043

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	15 Jan 2021 17:58:54

**US3542043**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:04:11
User entered 'l'	System	15 Jan 2021 17:58:54

**US3542043**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	22 Jan 2021 18:08:12

US3542043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered '21 Jan 2021'	(b) (4) Hannah Yellin (b) (4)	22 Jan 2021 18:08:12



**US3542043**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Hannah Yellin (b) (4)	22 Jan 2021 18:08:12

US3542043

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered empty.	(b) (4) Hannah Yellin (b) (4)	22 Jan 2021 18:08:12

US3542043

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User entered 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4) (b) (4)	22 Jan 2021 18:08:18

**US3542043**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'l'	System	22 Jan 2021 18:08:18

**US3542043**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'I'	System	22 Jan 2021 18:08:18
DataPoint set to visible.	System	22 Jan 2021 18:08:18

**US3542043**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:48:13

**US3542043**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:48:13

**US3542043**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:48:13



**US3542043**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'OLD29'	System	11 Feb 2021 16:48:13

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:48:41

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '10 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '10:22'	(b) (4), (b) (6)	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered '10 Feb 2021 10:22'	System	11 Feb 2021 16:48:41

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '98.1' F	(b) (4), (b) (6)	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Feb 2021 16:48:41



**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '62'	(b) (4), (b) (6)	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'bpm'	System	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '16'	(b) (4), (b) (6)	11 Feb 2021 16:48:41

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'breaths/min'	System	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '103'	(b) (4), (b) (6)	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'mmHg'	System	11 Feb 2021 16:48:41

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '61'	(b) (4), (b) (6)	11 Feb 2021 16:48:41



US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'mmHg'	System	11 Feb 2021 16:48:41

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '10 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '11:25'	(b) (4), (b) (6)	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered '10 Feb 2021 11:25'	System	11 Feb 2021 16:49:16

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '98.9' F	(b) (4), (b) (6)	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Feb 2021 16:49:16



**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '51'	(b) (4), (b) (6)	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'bpm'	System	11 Feb 2021 16:49:16

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '16'	(b) (4), (b) (6)	11 Feb 2021 16:49:16

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'breaths/min'	System	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User entered '106'	(b) (4), (b) (6)	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'mmHg'	System	11 Feb 2021 16:49:16

US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	19 Feb 2021 17:24:40
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 08:53:44
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	David Diemert (b) (4)	17 Feb 2021 14:05:02
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		11 Feb 2021 16:49:16
User entered '54'	(b) (4), (b) (6)	11 Feb 2021 16:49:16



US3542043

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'mmHg'	System	11 Feb 2021 16:49:16

**US3542043**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:47:42**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:03

**US3542043**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:47:42**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:03

**US3542043**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:51:19

**US3542043**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:19

**US3542043**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:19

**US3542043**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:19

**US3542043**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:19



**US3542043**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:19

**US3542043**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:47:42**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:19

US3542043

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:47:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered empty.	System	11 Feb 2021 16:51:19

**US3542043**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:47:42**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:51:35

US3542043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:35

US3542043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

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)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 16:51:35

US3542043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'mRNA-1273'	System	11 Feb 2021 16:51:35
DataPoint set to visible.	System	22 Jan 2021 18:08:18

US3542043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:51:35



**US3542043**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:47:42**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered '10:55'	(b) (4), (b) (6)	11 Feb 2021 16:51:35

US3542043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered '10 Feb 2021 10:55'	System	11 Feb 2021 16:51:35

US3542043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Feb 2021 16:51:35

US3542043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'ONCE'	System	11 Feb 2021 16:51:35

US3542043

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 16:51:35

**US3542043**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 16:52:26

**US3542043**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'l'	System	11 Feb 2021 16:52:26

**US3542043**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:07
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Feb 2021 18:37:05



**US3542043**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:07
User entered '17 Feb 2021'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Feb 2021 18:37:05

**US3542043**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erika Faust (b) (4)	19 Feb 2021 18:37:05

**US3542043**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:47:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:07
User entered empty.	(b) (4) Erika Faust (b) (4)	19 Feb 2021 18:37:05

US3542043

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:07
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	19 Feb 2021 18:37:08

**US3542043**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:47:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'l'	System	19 Feb 2021 18:37:08

**US3542043**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:26:55

**US3542043**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered '08 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:26:55

US3542043

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:42

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered 'Clinic (Clinic)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:26:55



**US3542043**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:47:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered 'OLD57'	System	09 Mar 2021 16:26:55

US3542043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:26:47

US3542043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:26:47

**US3542043**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:26:47

**US3542043**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered empty.	System	09 Mar 2021 16:26:47

US3542043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:26:47
	(b) (4)	

US3542043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:26:47

**US3542043**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:26:47
	(b) (4)	



**US3542043**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:26:47

**US3542043**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered empty.	System	09 Mar 2021 16:26:47

US3542043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:26:47

US3542043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered empty.	System	09 Mar 2021 16:26:47

US3542043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:26:47

**US3542043**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered empty.	System	09 Mar 2021 16:26:47

US3542043

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:26:47

**US3542043**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered empty.	System	09 Mar 2021 16:26:47



**US3542043**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24

**US3542043**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:47:42**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24

US3542043

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:27:04

**US3542043**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:47:42**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered empty.	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:27:04

US3542043

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:27:15

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered '08 Mar 2021'	(b) (4) Taylor Ladson (b) (4)	09 Mar 2021 16:27:15

**US3542043**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:42**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User signature succeeded.	David Diemert (b) (4)	10 Mar 2021 01:12:36
User entered '12:20'	(b) (4) Taylor Ladson (b) (4) (b) (4)	09 Mar 2021 16:27:15

**US3542043**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:47:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:51:24
User entered '08 Mar 2021 12:20'	System	09 Mar 2021 16:27:15



US3542043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:47:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:55
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 78 (09NOV2020) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 14:19:20
Query 'Per DM CLR: Per Safety Follow Up Diary Day 78 (09NOV2020) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Participant had a routine follow-up appointment with PCP, as noted in the source documents for this participant. ' (Site from DM).	David Diemert (b) (4) (b) (4)	05 Apr 2021 14:14:54
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 78 (09NOV2020) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:52:25
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:36
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:16:10
Signature has been broken.	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 16:43:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 16:43:02

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:47:42

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
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	16 Sep 2020 16:35:12
User entered 'No (N)' reason for change: Data Entry Error	System	16 Sep 2020 16:35:12
User entered empty; reason for change Data Entry Error	Hannah Yellin (b) (4)	16 Sep 2020 16:35:12
User entered 'Yes (Y)'	(b) (4)	
	System	26 Aug 2020 18:44:58
	Hannah Yellin (b) (4)	26 Aug 2020 18:44:58
	(b) (4)	
	Hannah Yellin (b) (4)	26 Aug 2020 18:44:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

[AEID](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please note that as per CCG COVID-19 symptoms should not be considered as AE and need to be entered under COVID diagnosis. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 06:47:08
Query 'Per CDM: Please note that as per CCG COVID-19 symptoms should not be considered as AE and need to be entered under COVID diagnosis. Please update accordingly.' answered with 'symptoms are entered on the COVID-19 symptom log only. Followed Moderna EDC entry guidance' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	20 Oct 2020 14:58:50
User opened query 'Per CDM: Please note that as per CCG COVID-19 symptoms should not be considered as AE and need to be entered under COVID diagnosis. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:11:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:31:24
User entered 'USA-US084-2020-mRNA-1273-P301000002'	System	29 Sep 2020 16:31:21
User entered 'New'	(b) (4), (b) (6)	29 Sep 2020 16:31:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:35:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:35:47
User signature succeeded.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:16:21
Data point term sent to Coder	System	29 Sep 2020 03:52:32
Coding entries removed.	David Diemert (b) (4) (b) (4)	29 Sep 2020 03:52:20
Signature has been broken.	David Diemert (b) (4) (b) (4)	29 Sep 2020 03:52:20
User entered 'Symptomatic Covid 19' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	29 Sep 2020 03:52:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:16:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 16:45:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 16:45:36
Data point term sent to Coder	System	17 Sep 2020 16:44:45
User entered 'upper respiratory tract infection'	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 16:44:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:52:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:52:20
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'No (N)'	(b) (4)	
	Taylor Ladson (b) (4)	17 Sep 2020 16:44:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '07 Sep 2020'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20



**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 16:44:20

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:52:20
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:52:20
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '15 Sep 2020'	(b) (4)	
	Taylor Ladson (b) (4)	17 Sep 2020 16:44:20
	(b) (4)	

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 16:44:20

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20



**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:47:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20



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**Form: Adverse Events (1)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Not Related (NOT RELATED)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 04:36:02
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Primary reason for dosing discontinuation was updated to "Due to SARS-CoV-2" per the following query: 'Per CDM: please consider selecting 'Due to SARS-CoV-2' and make all applicable updates" (Site from System).	Hannah Yellin (b) (4) (b) (4)	18 Nov 2020 16:50:12
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Nov 2020 16:45:53
User closed query 'Per DM CLR RQ: Per previous query response. Please ensure Investigational Product Withdrawn is reflected in dosing discontinuation if applicable else, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:19:50
User closed query 'Per DM CLR: Please note that Date of Dosing discontinuation is 05OCT2020 and is not within the timeframe of this AE. Review and reconcile AE and Dosing discontinuation eCRF pages as appropriate. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:19:25
Query 'Per DM CLR: Please note that Date of Dosing discontinuation is 05OCT2020 and is not within the timeframe of this AE. Review and reconcile AE and Dosing discontinuation eCRF pages as appropriate. Otherwise, clarify. ' answered with '05OCT2020 was the scheduled date of Dose 2 and therefore that is the date of dosing discontinuation since she was not given dose 2 per protocol' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	06 Nov 2020 20:54:40

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Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that Date of Dosing discontinuation is 05OCT2020 and is not within the timeframe of this AE. Review and reconcile AE and Dosing discontinuation eCRF pages as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:36:16
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		05 Nov 2020 19:07:37
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	05 Nov 2020 19:07:37
Query 'Per DM CLR RQ: Per previous query response. Please ensure Investigational Product Withdrawn is reflected in dosing discontinuation if applicable else, clarify in query response.' answered with 'Dosing Discontinuation Completed' (Site from DM).	Erika Faust (b) (4) (b) (4)	05 Nov 2020 19:02:48
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	05 Nov 2020 18:15:26
User opened query 'Per DM CLR RQ: Per previous query response. Please ensure Investigational Product Withdrawn is reflected in dosing discontinuation if applicable else, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 12:31:35
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 12:31:35

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'done' (Site from DM).	Elissa Malkin (b) (4)	30 Oct 2020 17:10:32
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.'	(b) (4), (b) (6)	30 Oct 2020 09:05:45
(Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.'	(b) (4), (b) (6)	12 Oct 2020 16:18:16
(Site from Safety).		
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.'	David Diemert (b) (4)	10 Oct 2020 19:10:16
answered with 'Updated.' (Site from Safety).	(b) (4)	
Signature has been broken.	David Diemert (b) (4)	10 Oct 2020 19:10:05
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	David Diemert (b) (4)	10 Oct 2020 19:10:05
	(b) (4)	
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.'	(b) (4), (b) (6)	05 Oct 2020 13:32:39
(Site from Safety).		
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (NONE)'	Taylor Ladson (b) (4)	17 Sep 2020 16:44:20
	(b) (4)	

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 15:00:10
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 17:50:04
User signature succeeded.	David Diemert (b) (4)	31 Oct 2020 18:29:05
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4)	30 Oct 2020 17:11:05
DataPoint Un-verified.	Elissa Malkin (b) (4)	30 Oct 2020 17:10:48
Signature has been broken.	Elissa Malkin (b) (4)	30 Oct 2020 17:10:48
User entered '0' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	30 Oct 2020 17:10:48
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:29:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '1'	Taylor Ladson (b) (4)	17 Sep 2020 16:44:20



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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 15:00:12
User signature succeeded.	David Diemert (b) (4)	31 Oct 2020 18:29:05
DataPoint Un-verified.	(b) (4)	
	Elissa Malkin (b) (4)	30 Oct 2020 17:10:48
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	30 Oct 2020 17:10:48
User entered '1' reason for change: Per Query Resolution	(b) (4)	
	Elissa Malkin (b) (4)	30 Oct 2020 17:10:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '0'	Taylor Ladson (b) (4)	17 Sep 2020 16:44:20
	(b) (4)	

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Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	(b) (4) Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User closed query 'PV Query: Please confirm the collection date of the test which resulted on 16 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:18:29
User closed query 'PV Query: Please provide the results of the immunogenicity assessment dated 24 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:18:28
User closed query 'PV Query: Please provide the results of the blood sample immunogenicity assessment dated 11 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:18:26
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:18:25
User closed query 'PV Query: Please confirm on the demographics page that White and Asian should be selected.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:18:23
Query 'PV Query: Please confirm the collection date of the test which resulted on 16 Sep 2020.' answered with 'The Day 1 NP swab that resulted on 16SEP2020 was collected on 11SEP2020.' (Site from Safety).	David Diemert (b) (4) (b) (4)	10 Oct 2020 19:14:16
Query 'PV Query: Please provide the results of the immunogenicity assessment dated 24 Aug 2020.' answered with 'I don't understand this query. We don't receive results of immunogenicity assessments.' (Site from Safety).	David Diemert (b) (4) (b) (4)	10 Oct 2020 19:12:27
Query 'PV Query: Please provide the results of the blood sample immunogenicity assessment dated 11 Sep 2020.' answered with 'I don't understand this query. We don't get results of immunogenicity assessments.' (Site from Safety).	David Diemert (b) (4) (b) (4)	10 Oct 2020 19:12:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Con Med already entered. No other intervention or treatment given.' (Site from Safety).	David Diemert (b) (4)	10 Oct 2020 19:11:19
Query 'PV Query: Please confirm on the demographics page that White and Asian should be selected.' answered with 'Confirmed' (Site from Safety).	Elissa Malkin (b) (4)	08 Oct 2020 19:34:50
User opened query 'PV Query: Please confirm the collection date of the test which resulted on 16 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:35:03
User opened query 'PV Query: Please provide the results of the blood sample immunogenicity assessment dated 11 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:33:27
User opened query 'PV Query: Please provide the results of the immunogenicity assessment dated 24 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:33:13
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:33:06
User opened query 'PV Query: Please confirm on the demographics page that White and Asian should be selected.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:32:55
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
Signature has been broken.	David Diemert (b) (4)	29 Sep 2020 04:05:29

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant had mild symptoms of rhinorrhea, nasal congestion, post-nasal drip and non-productive cough starting on 07SEP2020. No fever, chills, dyspnea, myalgias, arthralgias, loss of taste/smell, or GI symptoms. Illness visit Day 1 conducted on 11SEP2020; NP swab from that day was SARS-CoV-2 PCR negative. Saliva collected on 13SEP 2020 also PCR negative. Symptoms resolved on 14 SEP2020. Saliva collected on 15SEP2020 but further telemedicine visits and saliva collections discontinued thereafter due to report of negative Day 1 NP swab PCR received on 16SEP2020. However, late on 23SEP2020, the convalescent Day 5 (15SEP2020) saliva sample was reported as positive for SARS-CoV-2. Multiple ePIP exchanges between PI and PPD/Moderna on 24-25SEP2020 resulted in the decision that this would be considered a positive symptomatic COVID-19 case, with the Day 1 illness visit considered as 11SEP2020. Since symptoms had resolved on 14SEP2020 (confirmed via phone on 24SEP2020), additional telemedicine visits were not warranted. A convalescent Day 21 saliva sample will be collected on 01OCT2020 as well as a convalescent Day 29 visit on 08OCT2020. The second dose of vaccine/placebo will not be administered. It should be noted that the PI still considers the positive convalescent Day 5 saliva PCR result to be a false positive given the complete lack of correlation between clinical presentation/evolution, and the laboratory results.' reason for change: Data Entry Error	David Diemert (b) (4)	29 Sep 2020 04:05:29
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered empty.	Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Sep 2020 16:44:20



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Sep 2020 16:44:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User coded data point as SOC: Reproductive system and breast disorders, HLG: Cervix disorders (excl infections and inflammations), HLT: Cervix disorders NEC, PT: Cervical dysplasia, LLT: Low grade squamous intraepithelial lesion - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	05 Nov 2020 05:09:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 05:09:43
Data point term sent to Coder	System	04 Nov 2020 17:42:46
User entered 'Low grade squamous intraepithelial lesion of cervix'	Erika Faust (b) (4)	04 Nov 2020 17:42:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '6 Oct 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:42:37



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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:42:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37



US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

None

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	04 Nov 2020 20:27:10
User entered '1' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	04 Nov 2020 20:27:10
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Nov 2020 17:42:37
User entered '0'	Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:47:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:42:37

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 17:42:37

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 17:42:37

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:42**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Animal bite, LLT: Dog bite - version MedDRA\23.0.	Coder Import (b) (4)	10 Jan 2021 12:27:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Jan 2021 12:27:38
Data point term sent to Coder	System	08 Jan 2021 21:38:20
User entered 'Dog bite to the face'	Erika Faust (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '24 Dec 2020'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:38:14

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User entered empty.	System	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	15 Jan 2021 18:04:05
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	15 Jan 2021 18:04:05
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Yes (Y)'	(b) (4)	
	Erika Faust (b) (4)	08 Jan 2021 21:38:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	15 Jan 2021 18:04:05
User entered '31 Dec 2020' reason for change: New Information	(b) (4)	
	Erika Faust (b) (4)	15 Jan 2021 18:04:05
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4)	
	Erika Faust (b) (4)	08 Jan 2021 21:38:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User entered empty.	System	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:38:14



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

US3542043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

US3542043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

US3542043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

US3542043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Not Related (NOT RELATED)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
User closed query 'Per CDM: As the Adverse event started after last dose, please review and update the action taken with study drug from None to Not Applicable. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 05:17:01
Query 'Per CDM: As the Adverse event started after last dose, please review and update the action taken with study drug from None to Not Applicable. ' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4)	13 Jan 2021 20:47:13
Signature has been broken.	Elissa Malkin (b) (4)	13 Jan 2021 20:47:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	13 Jan 2021 20:47:05
User opened query 'Per CDM: As the Adverse event started after last dose, please review and update the action taken with study drug from None to Not Applicable. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:58:03
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'None (NONE)'	Erika Faust (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

US3542043

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'l'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14



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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:47:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '0'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	22 Jan 2021 18:10:34
Signature has been broken.	(b) (4)	
	Erika Faust (b) (4)	15 Jan 2021 18:04:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Erika Faust (b) (4)	15 Jan 2021 18:04:05
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erika Faust (b) (4)	08 Jan 2021 21:38:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:47:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:38:14

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User entered '0'	System	08 Jan 2021 21:38:14

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51
User entered 'I'	System	08 Jan 2021 21:38:14

**US3542043**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:05:51

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:47:42

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:55
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:40:31
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:27:58



US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:37:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:37:34
Data point term sent to Coder	System	25 Aug 2020 17:36:48
User entered 'Topiramate'	Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'migraine'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '50'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53
	(b) (4)	

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'twice daily (BID)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53
	(b) (4)	



US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53
	(b) (4)	

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'un Mar 2019'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:35:53

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Aug 2020 17:35:53



**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Aug 2020 17:35:53

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:32:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 22:32:27
Data point term sent to Coder	System	27 Oct 2020 20:16:42
Coding entries removed.	David Diemert (b) (4)	27 Oct 2020 20:16:12
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 19:09:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 19:09:38
Data point term sent to Coder	System	25 Aug 2020 17:36:52
User entered 'Cetirizine hci'	Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per subject source Concomitant Medication log has indication as Allergies. Please verify and update source as needed. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:37:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:37:10
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 20:37:08
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:37:06
Query 'Per subject source Concomitant Medication log has indication as Allergies. Please verify and update source as needed. ' answered with 'updated' (Site from CRA).	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 20:58:55
User opened query 'Per subject source Concomitant Medication log has indication as Allergies. Please verify and update source as needed. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 14:57:06
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
User closed query "'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 02:53:28
"		
' (Site from DM).		
Query "'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:16:18
"		
' answered with 'Clarified.' (Site from DM).		
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:16:12
Signature has been broken.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:16:12
User entered 'Dog ALLERGY' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:16:12

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Indication](#)

Audit	User	Time (GMT)
User opened query "'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.  ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 03:37:40
User signature succeeded.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User entered 'allergies'	David Diemert (b) (4) (b) (4) Taylor Ladson (b) (4) (b) (4)	27 Aug 2020 15:39:41  25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '10'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34



US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34
	(b) (4)	

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'as needed (PRN)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'un Jul 2020'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Yes (Y)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34



US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:36:34

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:36:34

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:36:34

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Aug 2020 17:38:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Aug 2020 17:38:33
Data point term sent to Coder	System	25 Aug 2020 17:37:53
User entered 'Mirena'	Taylor Ladson (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:51:14
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:58:34
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4)	06 Nov 2020 20:50:44
DataPoint Un-verified.	Elissa Malkin (b) (4)	06 Nov 2020 20:50:37
Signature has been broken.	Elissa Malkin (b) (4)	06 Nov 2020 20:50:37
User entered 'Yes (Y)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	06 Nov 2020 20:50:37
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:40:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'No (N)'	Taylor Ladson (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:40:42
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:40:18
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'contraception'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:37:23



US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'unk'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Other (OTHER)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'unknown'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'other (OTHER)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'continuous'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Other (OTHER)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'intrauterine'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'un Feb 2016'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:37:23



US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:51:24
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
DataPoint Un-verified.	(b) (4)	
	David Diemert (b) (4)	10 Nov 2020 15:05:37
Signature has been broken.	(b) (4)	
	David Diemert (b) (4)	10 Nov 2020 15:05:37
User entered 'No (N)' reason for change: New Information	(b) (4)	
	David Diemert (b) (4)	10 Nov 2020 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'Yes (Y)'	(b) (4)	
	Taylor Ladson (b) (4)	25 Aug 2020 17:37:23
	(b) (4)	

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:51:21
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
DataPoint Un-verified.	(b) (4) David Diemert (b) (4)	10 Nov 2020 15:05:37
Signature has been broken.	(b) (4) David Diemert (b) (4)	10 Nov 2020 15:05:37
User entered '03 Nov 2020' reason for change: New Information	(b) (4) David Diemert (b) (4)	10 Nov 2020 15:05:37
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered empty.	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:41:24
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:37:23

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
User entered empty.	System	25 Aug 2020 17:37:23

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
User entered empty.	System	25 Aug 2020 17:37:23

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:05
User entered empty.	System	25 Aug 2020 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 07:20:41
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 Oct 2020 07:20:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:36:56
Data point term sent to Coder	System	30 Sep 2020 13:52:25
User entered 'phenylephrine'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50



US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:08
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:09
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'symptomatic covid-19'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:12
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '10'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:13
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'mg (mg)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:15
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:16
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'as needed (PRN)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:18
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:19
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Oral (ORAL)'	(b) (4) Taylor Ladson (b) (4)	30 Sep 2020 13:51:50



US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:21
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered empty.	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:23
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '08 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '0'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:29
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'No (N)'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:30
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '11 Sep 2020'	(b) (4) Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 14:51:03
User signature succeeded.	David Diemert (b) (4)	03 Nov 2020 19:32:25
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = YES. However, Indication does not reflect any of the solicited events for this study. Please review and update response to 'Was this medication taken for a solicited event?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 09:29:01
Query 'Per DM CLR: Was this medication taken for solicited event?' = YES. However, Indication does not reflect any of the solicited events for this study. Please review and update response to 'Was this medication taken for a solicited event?' as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	30 Oct 2020 17:06:30
DataPoint Un-verified.	Elissa Malkin (b) (4) (b) (4)	30 Oct 2020 17:06:22
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	30 Oct 2020 17:06:22
User entered 'No (N)' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	30 Oct 2020 17:06:22
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = YES. However, Indication does not reflect any of the solicited events for this study. Please review and update response to 'Was this medication taken for a solicited event?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:29:29
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:36:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:36:56
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 13:51:50

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
User entered empty.	System	30 Sep 2020 13:51:50

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
User entered empty.	System	30 Sep 2020 13:51:50



**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:47:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:19
User entered empty.	System	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 23:31:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 23:31:50
Data point term sent to Coder	System	08 Jan 2021 21:37:19
User entered 'Amoxicillin'	Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Dog bite to the face'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '125'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'mg (mg)'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'twice daily (BID)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:37:16



US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Oral (ORAL)'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '27 Dec 2020'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered '0'	(b) (4) Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:23
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 09:10:07
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4)	27 Jan 2021 14:53:49
Signature has been broken.	Elissa Malkin (b) (4)	27 Jan 2021 14:53:06
User entered 'No (N)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	27 Jan 2021 14:53:06
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 23:08:59
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'Yes (Y)'	Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	31 Jan 2021 19:17:23
Signature has been broken.	Elissa Malkin (b) (4)	27 Jan 2021 14:53:06
User entered '03 Jan 2021' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	27 Jan 2021 14:53:06
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered empty.	Erika Faust (b) (4)	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:13
User entered 'No (N)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 21:37:16



**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User entered '2'	System	08 Jan 2021 21:37:16

**US3542043**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:47:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User entered '1'	System	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:11
User entered '804 (804)'	System	08 Jan 2021 21:37:16

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:47:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:55
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Yes (Y)'	(b) (4) Erika Faust (b) (4) (b) (4)	04 Nov 2020 17:45:19

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:47:42

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:14
Signature has been broken.	(b) (4)	
	Elissa Malkin (b) (4)	17 Nov 2020 20:57:16
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered '03 Nov 2020'	DeEnna Wedding (b) (4)	10 Nov 2020 19:24:56
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:47:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User closed query 'Per log subject had colposcopy. Please verify procedure and update source/EDC as needed. ' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4)	23 Nov 2020 22:07:31 20 Nov 2020 04:10:14
Query 'Per log subject had colposcopy. Please verify procedure and update source/EDC as needed. ' answered with 'updated' (Site from CRA). Signature has been broken.	Elissa Malkin (b) (4) Elissa Malkin (b) (4)	17 Nov 2020 20:55:38 17 Nov 2020 20:55:29
User entered 'colposcopy' reason for change: Data Entry Error	Elissa Malkin (b) (4)	17 Nov 2020 20:55:29
User opened query 'Per log subject had colposcopy. Please verify procedure and update source/EDC as needed. ' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4)	16 Nov 2020 15:42:01 12 Nov 2020 21:46:19
User entered 'colonoscopy'	DeEnna Wedding (b) (4)	10 Nov 2020 19:24:56

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:47:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) DeEnna Wedding (b) (4)	10 Nov 2020 19:24:56

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:47:42

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered empty.	(b) (4) DeEnna Wedding (b) (4)	10 Nov 2020 19:24:56
	(b) (4)	



US3542043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:42

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:13
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User closed query 'Per CDM: Per CCG, Date should be entered in (dd MMM yyyy) format. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:30:25
Query 'Per CDM: Per CCG, Date should be entered in (dd MMM yyyy) format. Please review and update accordingly.' answered with 'Date is entered in correct format.' (Site from DM).	Erika Faust (b) (4)	06 Nov 2020 14:22:41
User entered '05 Oct 2020' reason for change: Data Entry Error	Erika Faust (b) (4)	06 Nov 2020 14:22:24
User opened query 'Per CDM: Per CCG, Date should be entered in (dd MMM yyyy) format. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:02:24
User entered '5 Oct 2020' reason for change: Data Entry Error	Erika Faust (b) (4)	05 Nov 2020 20:09:56
User entered '30 Oct 2020'	Erika Faust (b) (4)	05 Nov 2020 18:15:26

US3542043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:42

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:13
User closed query 'Per CDM: please consider selecting 'Due to SARS-CoV-2' and make all applicable updates' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:32:42
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:14
Query 'Per CDM: please consider selecting 'Due to SARS-CoV-2' and make all applicable updates' answered with 'Updated to 'due to SARS-CoV-2' (Site from DM).	Hannah Yellin (b) (4)	18 Nov 2020 16:46:59
Signature has been broken.	Hannah Yellin (b) (4)	18 Nov 2020 16:45:53
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Per Query Resolution	Hannah Yellin (b) (4)	18 Nov 2020 16:45:53
User opened query 'Per CDM: please consider selecting 'Due to SARS-CoV-2' and make all applicable updates' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:06:12
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Erika Faust (b) (4)	05 Nov 2020 19:07:37
User entered 'Due to SARS-COV-2 (COVID)'	Erika Faust (b) (4)	05 Nov 2020 18:15:26

US3542043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:42

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:30:13
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:14
Signature has been broken.	(b) (4)	
	Hannah Yellin (b) (4)	18 Nov 2020 16:45:53
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Hannah Yellin (b) (4)	18 Nov 2020 16:45:53
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Erika Faust (b) (4)	05 Nov 2020 19:07:37
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	05 Nov 2020 18:15:26
	(b) (4)	

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'USA-US084-2020-MRNA-1273-P301000002'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21



**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'David'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'Diemert'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered '2300 Eye Street NW'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'Washington'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'DC'	System	29 Sep 2020 16:31:21



**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered '20037'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:33:08
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'US'	(b) (4) System	29 Sep 2020 16:31:41

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
	(b) (4)	
User entered '3'	System	12 Oct 2020 16:18:51
Signature has been broken.	System	09 Oct 2020 13:33:19
User entered '2'	System	09 Oct 2020 13:33:19
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:31:41

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'USA-US084-2020-MRNA-1273-P301000002'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21



**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'David'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'Diemert'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered '2300 Eye Street NW'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'Washington'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'DC'	System	29 Sep 2020 16:31:21



**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered '20037'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:33:08
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'US'	(b) (4) System	29 Sep 2020 16:31:41

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
	(b) (4)	
User entered '3'	System	12 Oct 2020 16:18:51
Signature has been broken.	System	09 Oct 2020 13:33:19
User entered '2'	System	09 Oct 2020 13:33:19
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:31:41

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:47:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '29/Sep/2020 12:31'	(b) (4) System	29 Sep 2020 16:31:41

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:47:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:33:08
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 16:31:41

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'USA-US084-2020-MRNA-1273-P301000002'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21



**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'David'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'Diemert'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered '2300 Eye Street NW'	System	29 Sep 2020 16:31:21



**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'Washington'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'DC'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered '20037'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:33:08
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'US'	(b) (4) System	29 Sep 2020 16:31:41

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
	(b) (4)	
User entered '3'	System	12 Oct 2020 16:18:51
Signature has been broken.	System	09 Oct 2020 13:33:19
User entered '2'	System	09 Oct 2020 13:33:19
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:31:41

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:47:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '09/Oct/2020 13:33'	(b) (4) System	09 Oct 2020 13:33:19

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:47:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:18:38
User entered 'l'	(b) (4), (b) (6)	09 Oct 2020 13:33:19

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'USA-US084-2020-MRNA-1273-P301000002'	System	29 Sep 2020 16:31:21



**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'No (N)'	System	29 Sep 2020 16:31:21

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'David'	System	29 Sep 2020 16:31:21



US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'Diemert'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered '2300 Eye Street NW'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'Washington'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered 'DC'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:31:36
User entered '20037'	System	29 Sep 2020 16:31:21

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:47:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
Reviewed for Safety.	(b) (4), (b) (6)	09 Oct 2020 13:33:08
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'US'	(b) (4) System	29 Sep 2020 16:31:41

US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
	(b) (4)	
User entered '3'	System	12 Oct 2020 16:18:51
Signature has been broken.	System	09 Oct 2020 13:33:19
User entered '2'	System	09 Oct 2020 13:33:19
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:31:41

**US3542043**

**Folder: SAE USA-US084-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:47:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '12/Oct/2020 12:18'	(b) (4) System	12 Oct 2020 16:18:51



US3542043

Folder: SAE USA-US084-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:47:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:27
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 16:18:51