

US3542043 (Prod: George Washington University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:35:31

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US3542043

Form: Participant Creation

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

Generated On: 26 Nov 2020 09:35:31

[Participant ID](#)

US3542043

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

US3542043

Folder: Screening

Form: Visit Date

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

Generated On: 26 Nov 2020 09:35:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3542043

Folder: Screening

Form: Demographics

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

Generated On: 26 Nov 2020 09:35:31

Date of Birth (MMM yyyy)	(b) (6) 1993
Age	26
Age Units	YEARS
Age (Derived)	26
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

US3542043

Folder: Screening

Form: Enrollment

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

Generated On: 26 Nov 2020 09:35:31

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 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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: 26 Nov 2020 09:35:31

Condition	ALLERGIES (DOGS)
Start date (dd MMM yyyy)	UN JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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: 26 Nov 2020 09:35:31

Condition	SYSTOLIC MURMUR
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	_____

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

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

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Folder: Screening

Form: Physical Examination

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

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 24 AUG 2020

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: Screening

Form: Risk of Exposure

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

Generated On: 26 Nov 2020 09:35:31

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 ☐

Specify

ECONOMIST

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

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Folder: Visit 1 Day 1

Form: Visit Date

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

Generated On: 26 Nov 2020 09:35:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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: 26 Nov 2020 09:35:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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 ☒

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

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 ☒

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

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 ☒

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

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 ☐

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:35:31

		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: 26 Nov 2020 09:35:31

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 ☒

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

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 ☒

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

Yes ☐	
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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
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: 26 Nov 2020 09:35:31

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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: 26 Nov 2020 09:35:31

Timepoint	Pre-Dose ☐
	Post-Dose ☒
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	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

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

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (dd MMM yyyy)	5 OCT 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Was the sample collected?

Yes ☒

No ☐

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	2 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	02 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:07 (24 HR)
Vital Signs Date and Time (derived)	02 NOV 2020 09:07
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	45 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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 ☐ 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 ☐
Have 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):	
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 ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

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30 JAN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

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27 FEB 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

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03 JUL 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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10 JUL 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

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17 JUL 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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31 JUL 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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07 AUG 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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14 AUG 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:35:31

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

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21 AUG 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

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28 AUG 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

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

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04 SEP 2022 23:59

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:35:31

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 ☐ 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: 26 Nov 2020 09:35:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

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 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

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) 24 Sep 2020 03:09:23

Generated On: 26 Nov 2020 09:35:31

Date of Contact	08 SEP 2020
Time of Contact	08:30
Date and Time of Contact (derived)	08 SEP 2020 08:30
Type of Contact	Clinic Visit - Scheduled☐ Clinical Visit - Unscheduled☐ Safety Call☒ Convalescent Tele-visit☐
Has the subject reported symptoms of SARS-COV-2?	Yes☒ No☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
v6.020 DTW (1102)	309 of 1822	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

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) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	12 SEP 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	97.9 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☐
	Mild ☒
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

v6.020 DTW (1102)

313 of 1822

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

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 (3)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
v6.020 DTW (1102)	317 of 1822	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

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 (4)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
v6.020 DTW (1102)	321 of 1822	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

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) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
v6.020 DTW (1102)	325 of 1822	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

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 (6)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
v6.020 DTW (1102)	329 of 1822	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

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 (7)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
v6.020 DTW (1102)	333 of 1822	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

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 (8)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	10 SEP 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

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 (9)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 SEP 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
v6.020 DTW (1102)	341 of 1822	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 21 Oct 2020 18:31:17

Generated On: 26 Nov 2020 09:35:31

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: COVID Diagnostic Test

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

Generated On: 26 Nov 2020 09:35:31

Date of Visit	11 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	15 SEP 2020
Type of Test Performed	Nasopharyngeal Swab ☐ Nasal Swab ☐ Saliva Test ☒ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

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

Generated On: 26 Nov 2020 09:35:31

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

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

Generated On: 26 Nov 2020 09:35:31

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 _____

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

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

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection

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

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:08 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:08
Height (<i>xxx.x</i>)	64 in
Weight (<i>xxx.x</i>)	165 lb
Temperature (<i>xxx.x</i>)	99.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:45 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:45
Height (<i>xxx.x</i>)	167 cm
Weight (<i>xxx.x</i>)	161 lb
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: Adverse Events

Form: Adverse Events Summary

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

Generated On: 26 Nov 2020 09:35:31

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)

Generated On: 26 Nov 2020 09:35:31

AEID	USA-US084-2020-MRNA-1273-P30 1000002
Adverse event	SYMPTOMATIC COVID 19
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)	07 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	14 SEP 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	
v6.020 DTW (1102)	359 of 1822

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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)

Generated On: 26 Nov 2020 09:35:31

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 ☐
Number of Days in ICU	
v6.020 DTW (1102)	363 of 1822

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☒ Unknown ☐
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: 26 Nov 2020 09:35:31

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) 12 Nov 2020 21:46:19

Generated On: 26 Nov 2020 09:35:31

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 ☐

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

Generated On: 26 Nov 2020 09:35:31

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAR 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 26 Nov 2020 09:35:31

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 ☐

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 26 Nov 2020 09:35:31

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 26 Nov 2020 09:35:31

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 ☐

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 26 Nov 2020 09:35:31

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	UN FEB 2016	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	03 NOV 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

Generated On: 26 Nov 2020 09:35:31

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 ☐

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

Generated On: 26 Nov 2020 09:35:31

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 11 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

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

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

Procedure/Surgery date (dd MMM yyyy)	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: 26 Nov 2020 09:35:31

Date of dosing discontinuation (dd MMM yyyy) 05 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	☐
SAE (specify)	☐
Death	☐
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Due to SARS-COV-2	☒
Other	☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3542043

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

SAEID	USA-US084-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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: 26 Nov 2020 09:35:31

SAEID	USA-US084-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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: 26 Nov 2020 09:35:31

SAEID	USA-US084-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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: 26 Nov 2020 09:35:31

SAEID	USA-US084-2020-MRNA-1273-P301000002
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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: 26 Nov 2020 09:35:31

[Participant ID](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:35:36
	(b) (4)	

US3542043

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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) (b) (4)	24 Aug 2020 12:49:38

US3542043

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'Clinic (Clinic)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:35:36
	(b) (4)	

US3542043

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	24 Aug 2020 13:35:36

US3542043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
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) (b) (4)	24 Aug 2020 12:49:39

US3542043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Age](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	25 Aug 2020 17:23:38

US3542043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '26'	System	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Sex](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Ethnicity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[White](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '1'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38

US3542043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Black](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Asian](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User entered '1'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:23:38

US3542043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered '0'	Taylor Ladson (b) (4)	25 Aug 2020 17:23:38
	(b) (4)	

US3542043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

[Other](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:35:31

Unknown

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Not reported](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered '24 Aug 2020'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04
	(b) (4)	

US3542043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	24 Aug 2020 13:36:04

US3542043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[Protocol Version](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered 'Amendment 2 (2)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04
	(b) (4)	

US3542043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04
	(b) (4)	

US3542043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered empty.	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04
	(b) (4)	

US3542043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered empty.	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04
	(b) (4)	

US3542043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:04
	(b) (4)	

US3542043

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:35:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 13:36:11

US3542043

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:35:31

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered 'Yes (Y)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:11
	(b) (4)	

US3542043

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:35:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
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.	(b) (4) 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) (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) (b) (4)	25 Aug 2020 17:22:36

US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	25 Aug 2020 17:22:36
	(b) (4)	

US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	25 Aug 2020 17:22:36

US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2011'	System	25 Aug 2020 17:22:36

US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:22:36

US3542043

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:35:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:22:36

US3542043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
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	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: 26 Nov 2020 09:35:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	25 Aug 2020 17:22:54

US3542043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	25 Aug 2020 17:22:54

US3542043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:22:54

US3542043

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:35:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:22:54

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Condition](#)

Audit	User	Time (GMT)
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) Coder Import (b) (4)	25 Aug 2020 17:24:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 17:24:36
Data point term sent to Coder	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: 26 Nov 2020 09:35:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered 'un UNK 2008'	Taylor Ladson (b) (4)	25 Aug 2020 17:23:05
	(b) (4)	

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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)	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)	06 Nov 2020 12:40:11
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	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)	25 Aug 2020 17:23:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Aug 2020 17:23:05
User entered empty.	System	25 Aug 2020 17:23:05
	Taylor Ladson (b) (4)	25 Aug 2020 17:23:05
	(b) (4)	

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:41
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	25 Aug 2020 17:23:05
	(b) (4)	

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	25 Aug 2020 17:23:05

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2008'	System	25 Aug 2020 17:23:05

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:23:05

US3542043

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:35:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:23:05

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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 17:25:01
	(b) (4)	

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 08:52'	System	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '167' cm	Taylor Ladson (b) (4)	25 Aug 2020 17:25:01
	(b) (4)	
DataPoint set to visible.	System	24 Aug 2020 13:36:11

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '159' lb	Taylor Ladson (b) (4)	25 Aug 2020 17:25:01
	(b) (4)	
DataPoint set to visible.	System	24 Aug 2020 13:36:11

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered missing code ND - Not Done.	Taylor Ladson (b) (4)	25 Aug 2020 17:25:01
	(b) (4)	

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered missing code ND - Not Done.	Taylor Ladson (b) (4)	25 Aug 2020 17:25:01
	(b) (4)	

US3542043

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 17:25:01

US3542043

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Was the physical examination performed?

Audit	User	Time (GMT)
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) David Diemert (b) (4)	13 Nov 2020 08:05:25 12 Nov 2020 21:46:19
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). Signature has been broken.	Elissa Malkin (b) (4) Elissa Malkin (b) (4)	11 Nov 2020 18:26:33 11 Nov 2020 18:26:02
User entered 'Yes (Y)' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	11 Nov 2020 18:26:02
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), (b) (6) David Diemert (b) (4)	11 Nov 2020 05:50:38 27 Aug 2020 15:39:52
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	26 Aug 2020 18:39:38
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	25 Aug 2020 17:24:20
User entered 'No (N)'	Taylor Ladson (b) (4)	25 Aug 2020 17:24:20

US3542043

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
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.	System	11 Nov 2020 18:26:26
	Elissa Malkin (b) (4)	11 Nov 2020 18:26:26
	(b) (4)	
User entered '24 Aug 2020' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	11 Nov 2020 18:26:26
	(b) (4)	
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System). User signature succeeded.	System	11 Nov 2020 18:26:02
	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered empty; reason for change Data Entry Error	Hannah Yellin (b) (4)	26 Aug 2020 18:39:38
	(b) (4)	
User entered '24 Aug 2020'	Taylor Ladson (b) (4)	25 Aug 2020 17:24:20
	(b) (4)	

US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If No, what is the reason?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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
	(b) (4)	

US3542043

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:35:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
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: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
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)	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).	System (b) (4)	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: 26 Nov 2020 09:35:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Test performed](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Result](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Collection date](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3542043

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Collection time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:24:07

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'No (N)'	Taylor Ladson (b) (4)	25 Aug 2020 17:28:58
	(b) (4)	

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Other](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

[Specify](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

No Risk Identified

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '1'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:28:58
	(b) (4)	

US3542043

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:35:31

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Other](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Specify](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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 17:27:28
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'Clinic (Clinic)'	Taylor Ladson (b) (4)	25 Aug 2020 17:27:28
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	25 Aug 2020 17:27:28

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

[Liver Disease](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'No (N)'	Caroline Thoreson (b) (4)	24 Aug 2020 13:36:32
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:35:31

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
	(b) (4)	
User entered 'No (N)'	Taylor Ladson (b) (4)	28 Sep 2020 19:39:38
	(b) (4)	
Amendment Manager: DataPoint set to visible.	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: 26 Nov 2020 09:35:31

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered missing code ND - Not Done.	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:31

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered missing code ND - Not Done.	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:31

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered missing code ND - Not Done.	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:31

Weight

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered missing code ND - Not Done.	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '08:52'	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 08:52'	System	25 Aug 2020 17:25:33

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '98.3' F	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'Oral (Oral)'	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '56'	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 17:25:33

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '15'	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 17:25:33

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '107'	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 17:25:33

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 17:25:33

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:31

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered missing code ND - Not Done.	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:35:31

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered missing code ND - Not Done.	Taylor Ladson (b) (4)	25 Aug 2020 17:25:33
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:26:08

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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 17:26:08
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 10:37'	System	25 Aug 2020 17:26:08

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '98.5' F	Taylor Ladson (b) (4)	25 Aug 2020 17:26:08
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'Oral (Oral)'	Taylor Ladson (b) (4)	25 Aug 2020 17:26:08
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '49'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:08

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 17:26:08

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 17:26:08

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 17:26:08

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 17:26:08

US3542043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
Signature has been broken.	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)	

US3542043

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
Signature has been broken.	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)	

US3542043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'No (N)'	Taylor Ladson (b) (4)	25 Aug 2020 17:26:20
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	25 Aug 2020 17:26:20
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Test performed](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Result](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
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) (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) (b) (4)	10 Sep 2020 17:25:35
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	10 Sep 2020 17:25:25
User entered 'No (N)' reason for change: Data Entry Error	Hannah Yellin (b) (4) (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) (b) (4)	27 Aug 2020 15:39:52
User entered empty.	Taylor Ladson (b) (4) (b) (4)	25 Aug 2020 17:26:20

US3542043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Collection date](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Collection time](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:26:20

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered empty.	Hira Qadir (b) (4)	24 Aug 2020 14:11:48
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 14:11:48

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '24 Aug 2020'	Hira Qadir (b) (4)	24 Aug 2020 14:11:48
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered '10:06'	Hira Qadir (b) (4)	24 Aug 2020 14:11:48
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 10:06'	System	24 Aug 2020 14:11:48

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Hira Qadir (b) (4)	24 Aug 2020 14:11:48
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	24 Aug 2020 14:11:48

US3542043

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 14:11:48

US3542043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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 17:26:52
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:39:52
User entered '09:18'	(b) (4) Taylor Ladson (b) (4)	25 Aug 2020 17:26:52

US3542043

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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 17:27:08
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:31

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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 17:27:08

US3542043

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:27:08

US3542043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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 17:26:29
	(b) (4)	

US3542043

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:26:29

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	24 Aug 2020 14:39:52
User entered 'Yes (Y)'	System	24 Aug 2020 14:39:52

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	24 Aug 2020 14:39:52
User entered '98.5'	System	24 Aug 2020 14:39:52

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	System	24 Aug 2020 14:39:52
User entered 'No (N)'	System	24 Aug 2020 14:39:52

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 14:39:52
User entered '24 Aug 2020 10:39'	System	24 Aug 2020 14:39:52

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	25 Aug 2020 00:31:43
User entered 'Yes (Y)'	System	25 Aug 2020 00:31:43

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-3d45-4702-91a8-8eec777d6a09'	System	26 Aug 2020 01:03:08
User entered 'Yes (Y)'	System	26 Aug 2020 01:03:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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-3d45-4702-91a8-8eec777d6a09'	System	26 Aug 2020 01:03:08
User entered '98.7'	System	26 Aug 2020 01:03:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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-3d45-4702-91a8-8eec777d6a09'	System	26 Aug 2020 01:03:08
User entered 'No (N)'	System	26 Aug 2020 01:03:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-3d45-4702-91a8-8eec777d6a09'	System	26 Aug 2020 01:03:08
User entered '25 Aug 2020 21:03'	System	26 Aug 2020 01:03:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	28 Aug 2020 05:13:27
User entered 'Yes (Y)'	System	28 Aug 2020 05:13:27

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	28 Aug 2020 05:13:27
User entered '97.7'	System	28 Aug 2020 05:13:27

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	System	28 Aug 2020 05:13:27
User entered 'No (N)'	System	28 Aug 2020 05:13:27

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Aug 2020 05:13:27
User entered '28 Aug 2020 01:13'	System	28 Aug 2020 05:13:27

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	30 Aug 2020 01:10:49
User entered 'Yes (Y)'	System	30 Aug 2020 01:10:49

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	30 Aug 2020 01:10:49
User entered '29 Aug 2020 21:10'	System	30 Aug 2020 01:10:49

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-ea4db6d30528'	System	31 Aug 2020 01:06:08
User entered 'Yes (Y)'	System	31 Aug 2020 01:06:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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-ea4db6d30528'	System	31 Aug 2020 01:06:08
User entered '98.2'	System	31 Aug 2020 01:06:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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-ea4db6d30528'	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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-ea4db6d30528'	System	31 Aug 2020 01:06:08
User entered '30 Aug 2020 21:06'	System	31 Aug 2020 01:06:08

US3542043

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 14:40:28
User entered '24 Aug 2020 10:40'	System	24 Aug 2020 14:40:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 00:32:19
User entered '24 Aug 2020 20:32'	System	25 Aug 2020 00:32:19

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:02:28
User entered 'None (1)'	System	26 Aug 2020 01:02:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:02:28
User entered 'No (N)'	System	26 Aug 2020 01:02:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:02:28
User entered 'No (N)'	System	26 Aug 2020 01:02:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Aug 2020 01:02:28
User entered '25 Aug 2020 21:02'	System	26 Aug 2020 01:02:28

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 'eccc0aae-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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 'eccc0aae-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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 'eccc0aae-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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 'eccc0aae-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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 'eccc0aae-690a-4c18-801a-f7b734b7fc38'	System	27 Aug 2020 01:06:47
User entered '26 Aug 2020 21:06'	System	27 Aug 2020 01:06:47

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Aug 2020 03:15:54
User entered '27 Aug 2020 23:15'	System	28 Aug 2020 03:15:54

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	30 Aug 2020 01:12:04
User entered '29 Aug 2020 21:12'	System	30 Aug 2020 01:12:04

US3542043

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	System	24 Aug 2020 14:41:05
User entered 'None (0)'	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	24 Aug 2020 14:41:05
User entered 'None (0)'	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	24 Aug 2020 14:41:05
User entered 'None (0)'	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	System	24 Aug 2020 14:41:05
User entered 'No (N)'	System	24 Aug 2020 14:41:05

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Aug 2020 00:32:39
User entered 'None (0)'	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	25 Aug 2020 00:32:39
User entered 'None (0)'	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	System	25 Aug 2020 00:32:39
User entered 'No (N)'	System	25 Aug 2020 00:32:39

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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-eef6d1468d98'	System	26 Aug 2020 01:02:51
User entered 'None (0)'	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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-eef6d1468d98'	System	26 Aug 2020 01:02:51
User entered 'None (0)'	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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-eef6d1468d98'	System	26 Aug 2020 01:02:51
User entered 'None (0)'	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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-eef6d1468d98'	System	26 Aug 2020 01:02:51
User entered 'None (0)'	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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-eef6d1468d98'	System	26 Aug 2020 01:02:51
User entered 'None (0)'	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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-eef6d1468d98'	System	26 Aug 2020 01:02:51
User entered 'None (0)'	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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-eef6d1468d98'	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: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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-eef6d1468d98'	System	26 Aug 2020 01:02:51
User entered '25 Aug 2020 21:02'	System	26 Aug 2020 01:02:51

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:06:57
User entered 'None (0)'	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:06:57
User entered 'None (0)'	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:06:57
User entered 'None (0)'	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:06:57
User entered 'None (0)'	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:06:57
User entered 'None (0)'	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:06:57
User entered 'None (0)'	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:06:57
User entered 'No (N)'	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	27 Aug 2020 01:06:57
User entered '26 Aug 2020 21:06'	System	27 Aug 2020 01:06:57

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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-eaef-4ec2-b4f8-443939fe5016'	System	28 Aug 2020 03:16:07
User entered 'None (0)'	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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-eaef-4ec2-b4f8-443939fe5016'	System	28 Aug 2020 03:16:07
User entered 'None (0)'	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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-eaef-4ec2-b4f8-443939fe5016'	System	28 Aug 2020 03:16:07
User entered 'None (0)'	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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-eaef-4ec2-b4f8-443939fe5016'	System	28 Aug 2020 03:16:07
User entered 'None (0)'	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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-eaef-4ec2-b4f8-443939fe5016'	System	28 Aug 2020 03:16:07
User entered 'None (0)'	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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-eaef-4ec2-b4f8-443939fe5016'	System	28 Aug 2020 03:16:07
User entered 'None (0)'	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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-eaef-4ec2-b4f8-443939fe5016'	System	28 Aug 2020 03:16:07
User entered 'No (N)'	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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-eaef-4ec2-b4f8-443939fe5016'	System	28 Aug 2020 03:16:07
User entered '27 Aug 2020 23:16'	System	28 Aug 2020 03:16:07

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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'	System	30 Aug 2020 01:12:26
User entered 'None (0)'	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	System	30 Aug 2020 01:12:26
User entered 'None (0)'	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	30 Aug 2020 01:12:26
User entered 'None (0)'	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	System	30 Aug 2020 01:12:26
User entered 'No (N)'	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	30 Aug 2020 01:12:26
User entered '29 Aug 2020 21:12'	System	30 Aug 2020 01:12:26

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:35:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	31 Aug 2020 01:06:37
User entered 'None (0)'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	31 Aug 2020 01:06:37
User entered 'None (0)'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
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-a055-3ed23b8e6cc0'	System	31 Aug 2020 01:06:37
User entered 'None (0)'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

CHILLS

Audit	User	Time (GMT)
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'	System	31 Aug 2020 01:06:37
User entered 'None (0)'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	System	31 Aug 2020 01:06:37
User entered 'No (N)'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	31 Aug 2020 01:06:37
User entered '30 Aug 2020 21:06'	System	31 Aug 2020 01:06:37

US3542043

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:29:17
	(b) (4)	
User entered '31 Aug 2020'	Taylor Ladson (b) (4)	01 Sep 2020 15:52:04
	(b) (4)	

US3542043

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:29:17
	(b) (4)	
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	01 Sep 2020 15:51:26
	(b) (4)	

US3542043

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 15:51:26

US3542043

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
Signature has been broken.	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: 26 Nov 2020 09:35:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
Signature has been broken.	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
	(b) (4)	
User signature succeeded.	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: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
Signature has been broken.	Taylor Ladson (b) (4)	18 Sep 2020 17:22:28
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4)	18 Sep 2020 17:22:28
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	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: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:55:58

US3542043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	15 Sep 2020 17:56:09
	(b) (4)	

US3542043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
	(b) (4)	
User entered '14 Sep 2020'	Madhu Balachandran	15 Sep 2020 17:56:09
	(b) (4)	

US3542043

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
	(b) (4)	
User entered 'Yes (Y)'	Madhu Balachandran	15 Sep 2020 17:56:16
	(b) (4)	

US3542043

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:56:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	06 Oct 2020 19:32:18
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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).	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: 26 Nov 2020 09:35:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	06 Oct 2020 19:32:18

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered '05 Oct 2020'	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered '12:02'	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered '98.3' F	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered 'Oral (Oral)'	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered '48'	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered '14'	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered '105'	Taylor Ladson (b) (4)	06 Oct 2020 19:33:16
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:35:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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).	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: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Oct 2020 19:33:16

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	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: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:33:20

US3542043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered 'No (N)'	Taylor Ladson (b) (4)	06 Oct 2020 19:31:46
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:31:46
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Test performed](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Result](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:33:59
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:35:31

[Collection time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:33:59

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
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)	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)	08 Oct 2020 02:53:49
User entered 'No (N)'	Taylor Ladson (b) (4)	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[If No, reason not given](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:31:40
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:31:40
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:31:40
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:31:40
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:35:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:31:40

US3542043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered 'Yes (Y)'	Taylor Ladson (b) (4)	06 Oct 2020 19:34:34
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered '12:14'	Taylor Ladson (b) (4)	06 Oct 2020 19:34:34
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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) (b) (4)	08 Oct 2020 02:53:49
User entered empty.	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: 26 Nov 2020 09:35:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	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: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:34:24
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	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: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:53:49
	(b) (4)	
User entered empty.	Taylor Ladson (b) (4)	06 Oct 2020 19:34:24
	(b) (4)	

US3542043

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 19:34:24

US3542043

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 19:34:06

US3542043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:20:22

US3542043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:20:22

US3542043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:20:22

US3542043

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:20:22

US3542043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	14 Oct 2020 02:21:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 18:20:30

US3542043

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 18:20:30

US3542043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 18:15:33
	(b) (4)	
User entered 'Yes (Y)'	David Diemert (b) (4)	11 Nov 2020 18:15:12
	(b) (4)	

US3542043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 18:15:33
	(b) (4)	
User entered '20 Oct 2020'	David Diemert (b) (4)	11 Nov 2020 18:15:12
	(b) (4)	

US3542043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 18:15:33
User entered 'Contact Made (CONTACT MADE)'	David Diemert (b) (4)	11 Nov 2020 18:15:12

US3542043

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	11 Nov 2020 18:15:33
User entered empty.	David Diemert (b) (4)	11 Nov 2020 18:15:12

US3542043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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)'	DeEnna Wedding (b) (4)	27 Oct 2020 17:33:56

US3542043

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 17:33:56

US3542043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	27 Oct 2020 17:34:08
	(b) (4)	

US3542043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
	(b) (4)	
User entered '26 Oct 2020'	DeEnna Wedding (b) (4)	27 Oct 2020 17:34:08
	(b) (4)	

US3542043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	DeEnna Wedding (b) (4)	27 Oct 2020 17:34:08
	(b) (4)	

US3542043

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:35:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	27 Oct 2020 17:34:08
	(b) (4)	

US3542043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	29 Oct 2020 03:22:24
	(b) (4)	
User entered 'Yes (Y)'	DeEnna Wedding (b) (4)	27 Oct 2020 17:34:13
	(b) (4)	

US3542043

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 17:34:13

US3542043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 17:37:05
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered '2 Nov 2020'	Erika Faust (b) (4)	04 Nov 2020 17:37:05
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Clinic (Clinic)'	Erika Faust (b) (4)	04 Nov 2020 17:37:05
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	04 Nov 2020 17:37:05

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 17:37:40
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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) (b) (4)	06 Nov 2020 14:33:26
User entered '02 Nov 2020' reason for change: Data Entry Error	Erika Faust (b) (4) (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) (b) (4)	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered '09:07'	Erika Faust (b) (4)	04 Nov 2020 17:37:40
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered '98.4' F	Erika Faust (b) (4)	04 Nov 2020 17:37:40
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Oral (Oral)'	Erika Faust (b) (4)	04 Nov 2020 17:37:40
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:37:40
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered '45'	Erika Faust (b) (4)	04 Nov 2020 17:37:40
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered '16'	Erika Faust (b) (4)	04 Nov 2020 17:37:40
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered '107'	Erika Faust (b) (4)	04 Nov 2020 17:37:40
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered '70'	Erika Faust (b) (4)	04 Nov 2020 17:37:40
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 17:37:40

US3542043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	04 Nov 2020 17:37:46
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:37:46
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:14
	(b) (4)	
User entered '2 Nov 2020'	Erika Faust (b) (4)	04 Nov 2020 17:38:01
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:14
	(b) (4)	
User entered '09:24'	Erika Faust (b) (4)	04 Nov 2020 17:38:01
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:35:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 17:38:05
	(b) (4)	

US3542043

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:35:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:38:05

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[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: '2020-11-02T09:31:29', 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: 26 Nov 2020 09:35:31

Have you been exposed to someone with 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: '2020-11-02T09:31:31', 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: 26 Nov 2020 09:35:31

[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: '2020-11-02T09:31:34', User OID: 'PatientReportedOutcome (US3542043)', ODM File OID: '7147cb37-f14c-41cc-b2fa-67305964fe11'	System	09 Nov 2020 15:35:17
User entered '02 Nov 2020 09:31:34'	System	09 Nov 2020 15:35:17

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[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: '2020-11-09T10:35:43', 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: 26 Nov 2020 09:35:31

Have you been exposed to someone with 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: '2020-11-09T10:35:41', 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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 09:35:31

[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: '2020-11-09T10:35:49', 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

US3542043

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 01:33:43

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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 Oct 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: 26 Nov 2020 09:35:31

[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 Oct 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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 01:33:43

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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 Oct 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: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 01:33:43

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:43
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 01:33:43

US3542043

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

[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 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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:35:31

[Date of Contact](#)

Audit	User	Time (GMT)
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)	17 Sep 2020 17:05:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:35:31

[Time of Contact](#)

Audit	User	Time (GMT)
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).	(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).	(b) (4)	17 Sep 2020 17:05:43
User entered empty.	System	17 Sep 2020 17:05:43
	Hannah Yellin (b) (4)	17 Sep 2020 17:05:43
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:35:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Type of Contact](#)

Audit	User	Time (GMT)
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)	17 Sep 2020 17:05:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:35:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
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)'	Hannah Yellin (b) (4)	17 Sep 2020 17:05:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:35:31

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
Signature has been broken.	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: 26 Nov 2020 09:35:31

[Date](#)

Audit	User	Time (GMT)
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 17:06:43
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:35:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '98'	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: 26 Nov 2020 09:35:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:35:31

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '99.4' F	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: 26 Nov 2020 09:35:31

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Cough](#)

Audit	User	Time (GMT)
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 17:06:43
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:35:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) 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: 26 Nov 2020 09:35:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) 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: 26 Nov 2020 09:35:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:06:43

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:35:31

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) 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: 26 Nov 2020 09:35:31

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:06:43
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
Signature has been broken.	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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '12 Sep 2020'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '98'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '97.9' F	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:07:35

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Mild (Mild)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:35:31

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:07:35
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
Signature has been broken.	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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '13 Sep 2020'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '0'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '98'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Sep 2020 17:08:02

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '98.2' F	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
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 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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 17:08:02
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:02
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:35:31

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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 (4)

Generated On: 26 Nov 2020 09:35:31

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
Signature has been broken.	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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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '14 Sep 2020'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '0'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '99'	(b) (4) Hannah Yellin (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: 26 Nov 2020 09:35:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Sep 2020 17:08:27

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '98.4' F	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:35:31

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:27
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
Signature has been broken.	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: 26 Nov 2020 09:35:31

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '15 Sep 2020'	(b) (4) Hannah Yellin (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: 26 Nov 2020 09:35:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) 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: 26 Nov 2020 09:35:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '99'	(b) (4) Hannah Yellin (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: 26 Nov 2020 09:35:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Sep 2020 17:08:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '98.3' F	Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) 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: 26 Nov 2020 09:35:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
	(b) (4)	
Signature has been broken.	Erika Faust (b) (4)	16 Oct 2020 18:11:27
	(b) (4)	
User entered 'None (None)' reason for change: New Information	Erika Faust (b) (4)	16 Oct 2020 18:11:27
	(b) (4)	
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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
	(b) (4)	
User entered 'None (None)' reason for change: New Information	Erika Faust (b) (4)	16 Oct 2020 18:11:27
	(b) (4)	
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:35:31

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:08:53
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
	(b) (4)	
Signature has been broken.	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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Date](#)

Audit	User	Time (GMT)
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)	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)	23 Sep 2020 15:16:10
User entered '16 Sep 2020'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '0'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:09:52

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '98'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Sep 2020 17:09:52

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered '98.2' F	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'None (None)'	(b) (4) Hannah Yellin (b) (4)	17 Sep 2020 17:09:52

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	Hannah Yellin (b) (4)	17 Sep 2020 17:09:52
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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: 26 Nov 2020 09:35:31

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
	(b) (4)	
User entered 'None (None)'	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 (7)

Generated On: 26 Nov 2020 09:35:31

[Symptom Day](#)

Audit	User	Time (GMT)
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
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:35:31

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '07 Sep 2020'	(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)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
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 16:02:51
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Temperature](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Cough](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Fatigue](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Body Aches](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Headache](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:35:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Nausea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Vomiting](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Diarrhea](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Sore Throat](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered 'Day 4 (Day 4)'	(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: 26 Nov 2020 09:35:31

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '10 Sep 2020'	(b) (4) 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: 26 Nov 2020 09:35:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
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 16:03:31
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation](#)

Audit	User	Time (GMT)
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)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:03:31

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Temperature](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Chills](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Cough](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Fatigue](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Body Aches](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Headache](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Nausea](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Vomiting](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Diarrhea](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:35:31

[Sore Throat](#)

Audit	User	Time (GMT)
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 (9)

Generated On: 26 Nov 2020 09:35:31

[Symptom Day](#)

Audit	User	Time (GMT)
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
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	30 Sep 2020 22:36:56
User entered '08 Sep 2020'	(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: 26 Nov 2020 09:35:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:09:40

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Temperature](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Chills](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Cough](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Fatigue](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Body Aches](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Headache](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Nausea](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Vomiting](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Diarrhea](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:35:31

[Sore Throat](#)

Audit	User	Time (GMT)
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)	

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:35:31

[Date of Visit](#)

Audit	User	Time (GMT)
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)	17 Sep 2020 17:10:14

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:35:31

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
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)'	Hannah Yellin (b) (4)	17 Sep 2020 17:10:14

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:35:31

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
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). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4)	01 Oct 2020 05:37:05 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). 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). Signature has been broken.	David Diemert (b) (4) System	29 Sep 2020 03:49:03 29 Sep 2020 03:48:11
User entered 'Yes (Y)' reason for change: Data Entry Error User signature succeeded.	David Diemert (b) (4) David Diemert (b) (4)	29 Sep 2020 03:48:11 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

Generated On: 26 Nov 2020 09:35:31

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:16:21
Signature has been broken.	David Diemert (b) (4)	29 Sep 2020 03:48:11
User entered '15 Sep 2020' 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 '11 Sep 2020'	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

Generated On: 26 Nov 2020 09:35:31

Type of Test Performed

Audit	User	Time (GMT)
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	David Diemert (b) (4)	27 Oct 2020 20:12:42
NEGATIVE. Only the Day 5 convalescent saliva sample PCR was positive.' (Site from DM).	(b) (4)	
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).	(b) (4), (b) (6)	26 Oct 2020 18:57:57
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:34:54
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
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	(b) (4)	
	David Diemert (b) (4)	29 Sep 2020 03:48:11
User signature succeeded.	(b) (4)	
	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4)	
	Hannah Yellin (b) (4)	17 Sep 2020 17:10:14
	(b) (4)	

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Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:35:31

[Other, specify](#)

Audit	User	Time (GMT)
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.	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

Generated On: 26 Nov 2020 09:35:31

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
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)	17 Sep 2020 17:10:14

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Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:35:31

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
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.	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

Generated On: 26 Nov 2020 09:35:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
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.	Hannah Yellin (b) (4)	17 Sep 2020 17:10:14

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:35:31

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 03:48:11
User entered '0'	System	17 Sep 2020 17:10:14

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
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)'	David Diemert (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: 26 Nov 2020 09:35:31

[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[End Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[End Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Heart Rate](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level?

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[End Date](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[Oxygen Saturation](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[End Date](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[PaO2](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
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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Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[End Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[End Date](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Start Date](#)

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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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[End Date](#)

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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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[ECMO?](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

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[Start Date](#)

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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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

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[End Date](#)

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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.	David Diemert (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: 26 Nov 2020 09:35:31

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

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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.	David Diemert (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: 26 Nov 2020 09:35:31

[End Date](#)

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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.	David Diemert (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: 26 Nov 2020 09:35:31

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

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Folder: Covid-19 Assessment 08 Sep 2020

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[Start Date](#)

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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.	David Diemert (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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[End Date](#)

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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.	David Diemert (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: 26 Nov 2020 09:35:31

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

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[Start Date](#)

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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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[Start Date](#)

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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.	David Diemert (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: 26 Nov 2020 09:35:31

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

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[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[Clinical Evidence](#)

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

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[Date of Assessment](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[Radiographical Evidence](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
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.	David Diemert (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: 26 Nov 2020 09:35:31

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[Start Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:35:31

[End Date](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 03:49:53

US3542043

Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:35:31

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
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	David Diemert (b) (4)	29 Sep 2020 03:44:49
User entered 'Yes (Y)'	David Diemert (b) (4)	29 Sep 2020 03:44:13

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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)'	David Diemert (b) (4)	29 Sep 2020 04:07:25

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:35:31

[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'	David Diemert (b) (4)	29 Sep 2020 04:07:25

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:35:31

[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)'	David Diemert (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:35:31

[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'	David Diemert (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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)	29 Sep 2020 04:08:05
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)	29 Sep 2020 04:07:38
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 (3)

Generated On: 26 Nov 2020 09:35:31

[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.	David Diemert (b) (4)	29 Sep 2020 04:07:38

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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)	29 Sep 2020 04:08:05
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)	29 Sep 2020 04:07:38
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: 26 Nov 2020 09:35:31

[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.	David Diemert (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:35:31

[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)	29 Sep 2020 04:08:05
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)	29 Sep 2020 04:07:38
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: 26 Nov 2020 09:35:31

[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.	David Diemert (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:35:31

[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)	05 Oct 2020 01:36:27
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)	29 Sep 2020 04:07:38
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: 26 Nov 2020 09:35:31

[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	David Diemert (b) (4)	05 Oct 2020 01:36:27
User entered empty.	David Diemert (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:35:31

[Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[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)	

US3542043

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:35:31

[Date of Collection](#)

Audit	User	Time (GMT)
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)	14 Oct 2020 02:21:42
User entered '13 Oct 2020' reason for change: New Information	(b) (4) Hannah Yellin (b) (4)	13 Oct 2020 15:35:24
User entered empty.	(b) (4) David Diemert (b) (4)	29 Sep 2020 04:07:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 04:23:15

US3542043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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'	David Diemert (b) (4)	29 Sep 2020 04:23:15

US3542043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 04:23:15

US3542043

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	29 Sep 2020 04:23:15

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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'	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

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

Audit	User	Time (GMT)
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'	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Weight (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
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	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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'	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
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'	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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'	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
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'	David Diemert (b) (4)	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 13:48:38

US3542043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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)'	David Diemert (b) (4)	29 Sep 2020 04:23:29

US3542043

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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'	David Diemert (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: 26 Nov 2020 09:35:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
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)'	David Diemert (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: 26 Nov 2020 09:35:31

[Date of Collection](#)

Audit	User	Time (GMT)
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'	David Diemert (b) (4)	29 Sep 2020 04:23:45

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
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)'	Hannah Yellin (b) (4)	13 Oct 2020 15:33:53

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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)	13 Oct 2020 15:33:53

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
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)'	Hannah Yellin (b) (4)	13 Oct 2020 15:33:53

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:35:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	13 Oct 2020 15:33:53

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered 'Yes (Y)'	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '13 Oct 2020'	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '08:45'	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

Height (xxx.x)

Audit	User	Time (GMT)
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).	(b) (4)	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	(b) (4)	19 Oct 2020 19:40:48
DataPoint Verified.	Hannah Yellin (b) (4)	14 Oct 2020 18:17:19
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 15:34:33
User entered empty.	System	13 Oct 2020 15:34:33
DataPoint set to visible.	Hannah Yellin (b) (4)	13 Oct 2020 15:33:53
	(b) (4)	
	System	

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (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: 26 Nov 2020 09:35:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '98.8' F	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered 'Oral (Oral)'	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered empty.	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '62'	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '14'	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '112'	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:17:19
User entered '69'	Hannah Yellin (b) (4) (b) (4)	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:35:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:34:33

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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)	13 Oct 2020 15:34:51

US3542043

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:35:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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)	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: 26 Nov 2020 09:35:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
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 'Yes (Y)'	(b) (4) Hannah Yellin (b) (4)	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: 26 Nov 2020 09:35:31

[Date of Collection](#)

Audit	User	Time (GMT)
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)	13 Oct 2020 15:35:03

US3542043

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:35:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:42:36
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
Signature has been broken.	(b) (4)	
	Taylor Ladson (b) (4)	17 Sep 2020 16:43:02
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Ladson (b) (4)	17 Sep 2020 16:43:02
	(b) (4)	
User signature succeeded.	David Diemert (b) (4)	17 Sep 2020 04:16:59
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:35:12
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	Hannah Yellin (b) (4)	16 Sep 2020 16:35:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 18:44:58
User entered empty; reason for change Data Entry Error	Hannah Yellin (b) (4)	26 Aug 2020 18:44:58
	(b) (4)	
User entered 'Yes (Y)'	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: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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.	David Diemert (b) (4)	29 Sep 2020 03:52:20
User entered 'Yes (Y)' reason for change: Data Entry Error	David Diemert (b) (4)	29 Sep 2020 03:52:20
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered 'No (N)'	Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 16:44:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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.	David Diemert (b) (4)	29 Sep 2020 03:52:20
User entered '14 Sep 2020' reason for change: Data Entry Error	David Diemert (b) (4)	29 Sep 2020 03:52:20
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:16:10
User entered '15 Sep 2020'	Taylor Ladson (b) (4)	17 Sep 2020 16:44:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 16:44:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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)	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)	06 Nov 2020 20:54:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

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) (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. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:05:45
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:08:08
User signature succeeded.	David Diemert (b) (4) (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.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:18:16
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.' answered with 'Updated.' (Site from Safety).	David Diemert (b) (4) (b) (4)	10 Oct 2020 19:10:16
Signature has been broken.	David Diemert (b) (4) (b) (4)	10 Oct 2020 19:10:05
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	David Diemert (b) (4) (b) (4)	10 Oct 2020 19:10:05
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.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:32:39
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:16:10
User entered 'None (NONE)'	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: 26 Nov 2020 09:35:31

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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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) (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)	

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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)	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)	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)	10 Oct 2020 19:12:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:35:31

[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) (b) (4)	29 Sep 2020 04:05:29
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:16:10
User entered empty.	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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Sep 2020 16:44:20

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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)

Generated On: 26 Nov 2020 09:35:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered '6 Oct 2020'	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[AE start 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)

Generated On: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

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
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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)

Generated On: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'No (N)'	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Nov 2020 20:27:10
User entered '1' reason for change: Per Query Resolution	Elissa Malkin (b) (4)	04 Nov 2020 20:27:10
	(b) (4)	
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)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	Erika Faust (b) (4)	04 Nov 2020 17:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 17:42:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:35:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:42:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:35:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
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)'	Taylor Ladson (b) (4)	25 Aug 2020 17:27:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:35:53

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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) (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) (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) (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) (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) (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) (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) (b) (4)	25 Aug 2020 17:36:34

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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)	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) (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)	27 Oct 2020 20:16:18
"		
' answered with 'Clarified.' (Site from DM).		
DataPoint Un-verified.	David Diemert (b) (4)	27 Oct 2020 20:16:12
Signature has been broken.	David Diemert (b) (4)	27 Oct 2020 20:16:12
User entered 'Dog ALLERgy' reason for change: Per Query Resolution	David Diemert (b) (4)	27 Oct 2020 20:16:12

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:31

[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) (b) (6)	23 Oct 2020 03:37:40
User signature succeeded.	(b) (4), (b) (6) (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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 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: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
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) (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) (b) (4)	06 Nov 2020 20:50:44
DataPoint Un-verified.	Elissa Malkin (b) (4) (b) (4)	06 Nov 2020 20:50:37
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	06 Nov 2020 20:50:37
User entered 'Yes (Y)' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (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) (b) (4)	27 Aug 2020 15:39:41
User entered 'No (N)'	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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[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 'unk'	(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: 26 Nov 2020 09:35:31

[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 'Other (OTHER)'	(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: 26 Nov 2020 09:35:31

[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 'unknown'	(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: 26 Nov 2020 09:35:31

[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 'other (OTHER)'	(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: 26 Nov 2020 09:35:31

[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 'continuous'	(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: 26 Nov 2020 09:35:31

[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 'Other (OTHER)'	(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: 26 Nov 2020 09:35:31

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 '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: 26 Nov 2020 09:35:31

[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 Feb 2016'	(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: 26 Nov 2020 09:35:31

[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 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
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)	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: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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.	David Diemert (b) (4)	10 Nov 2020 15:05:37
Signature has been broken.	David Diemert (b) (4)	10 Nov 2020 15:05:37
User entered '03 Nov 2020' reason for change: New Information	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.	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: 26 Nov 2020 09:35:31

[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 17:37:23

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:35:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

[Dose per administration](#)

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

[Dose unit](#)

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

If route of administration is Other, specify

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

[Ongoing?](#)

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:35:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 13:51:50

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:35:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Yes (Y)'	Erika Faust (b) (4)	04 Nov 2020 17:45:19
	(b) (4)	

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:35:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:14
	(b) (4)	
Signature has been broken.	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)	

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	DeEnna Wedding (b) (4)	10 Nov 2020 19:24:56
	(b) (4)	

US3542043

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:35:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	12 Nov 2020 21:46:19
	(b) (4)	
User entered empty.	DeEnna Wedding (b) (4)	10 Nov 2020 19:24:56
	(b) (4)	

US3542043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:31

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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) (b) (4)	06 Nov 2020 14:22:41
User entered '05 Oct 2020' reason for change: Data Entry Error	Erika Faust (b) (4) (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) (b) (4)	05 Nov 2020 20:09:56
User entered '30 Oct 2020'	Erika Faust (b) (4) (b) (4)	05 Nov 2020 18:15:26

US3542043

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:35:31

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: please consider selecting 'Due to SARS-CoV-2' and make all applicable updates' (Site from DM). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4)	20 Nov 2020 04:32:42 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). Signature has been broken.	Hannah Yellin (b) (4) Hannah Yellin (b) (4)	18 Nov 2020 16:46:59 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). User signature succeeded.	(b) (4), (b) (6) David Diemert (b) (4)	18 Nov 2020 16:06:12 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: 26 Nov 2020 09:35:31

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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.

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 '1'	(b) (4) (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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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.

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 '1'	(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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

[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: 26 Nov 2020 09:35:31

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.

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 '1'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:18:51